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Annual Trending Report

January–December 2001

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Quality Assurance Program Annual Trending Report

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EXECUTIVE SUMMARY

This report documents the analysis of Quality Assurance (QA) deficiencies to identify trends adverse to quality for the National Spent Nuclear Fuel Program (NSNFP) and Independent Spent Fuel Storage Installations (ISFSI) under Nuclear Regulatory Commission license granted to the U.S. Department of Energy (DOE). Deficiencies are identified as Deficiency Reports (DR) and Corrective Action Request (CAR). DR/CAR reports tracked in the National Spent Nuclear Fuel Program (NSNFP) QA Corrective Action Tracking Trending System database were categorized into the following four groups for analysis:

- NSNFP Project Support Organization (PSO) and QA
- DOE Spent Nuclear Fuel (SNF) Sites
- NSNFP suppliers
- ISFSI.

Data for individual organizations were analyzed. This analysis identified the following organization-specific results:

NSNFP PSO and QA

Trends adverse to quality were identified in subject codes and direct cause codes for the deficiencies issued against the NSNFP. No adverse trends were identified as a result of the evaluation of root cause codes and timeliness of corrective action.

Analysis of subject codes and direct cause codes indicate an increasing frequency and high frequency of occurrence related to: not conducting work to approved procedures, and procedures not used or used improperly. Additionally, direct cause codes indicate an adverse trend related to procedures not describing how requirements will be implemented. The increase in frequency and high frequency of occurrence of subject and direct cause codes represents a trend adverse to quality. However, this adverse trend has been addressed as a part of corrective action for Deficiency Report 01-NSNFP-AU-001-DR-007 and 01-QAMA-9/18-DR-001. Revised NSNFP procedures were issued with an effective date of 1/15/02, to improve usability of procedures, and training of the NSNFP staff to the new procedures was conducted prior to the effective date of the procedures. Effectiveness of the revised procedures will be evaluated as a part of the NSNFP QA internal audit for FY 2002. Additionally, a commitment has been made to OCRWM OQA to perform a root cause analysis to determine if additional action is required for Deficiency Report 01-NSNFP-AU-001-DR-007.

No further action is requested by this report.

Hanford SNF

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action. The evaluation of deficiency codes of the Hanford SNF program found continued satisfactory performance, as reflected by the results of the NSNFP QA audits and surveillance.

No further action is requested by this report.

INEEL SNF

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action.

The INEEL SNF Program was last audited in 1998. This audit resulted in deficiencies addressing a major part of the INEEL SNF QA Program. In the 2000 NSNFP QA Annual Trending Report, the INEEL-SNF Program was identified as owning the longest duration of open DR/CAR reports. All of the deficiencies opened in 1998 were closed during 2001. A qualification audit, scheduled for 2001, has been re-scheduled for 2002.

No further action is requested by this report.

ORNL SNF

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action.

The evaluation of deficiency codes for the ORNL SNF QA program found continued satisfactory performance in 2001. The low activity level at ORNL has resulted in the delay of the NSNFP annual audit. The scope of this audit was intended to be a closeout audit at ORNL, as all NSNFP related activities are to be completed.

No further action is requested by this report.

Savannah River Site SNF

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action.

The annual audit of SRS was delayed within the fiscal year, resulting in trend data not being available within the calendar year of 2001. This delay is due in part to funding issues at SRS that will result in the demobilization of the melt dilute process for spent nuclear fuel at SRS. Additionally, reduced funding for the NSNFP QA program resulted in a reduction in surveillance of SRS SNF activities. The lack of audit and surveillance results precludes

performing an analysis of the performance of SRS for implementation of the NSNFP approved QA program.

Corrective Action Request, 01-SRS-02/22-01-CAR-001, issued as a result of last years NSNFP trend analysis has not been satisfactorily resolved by SRS. The failure of SRS to provide timely corrective action to the significant condition adverse to quality has been addressed by telephone conference with SRS SNF and NSNFP QA, and resolution is in process.

No further action is requested by this report.

NSNFP Suppliers

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action for any of the NSNFP Suppliers.

ISFSI

No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action. However analysis did identify the emergence of a repeated occurrence of a direct cause of failure to use procedures or use procedures improperly. The repeated occurrence did not represent a trend adverse to quality, however, ISFSI management should evaluate or monitor personnel performance to assure a trend adverse to quality does not develop over the next calendar year. No response is requested to this comment.

No further action is requested by this report.

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National Spent Nuclear Fuel Program
Quality Assurance Program Annual Trending Report

1. INTRODUCTION

1.1 Purpose and Scope

This report documents the analysis of Quality Assurance (QA) deficiencies for the identification of trends adverse to quality in the National Spent Nuclear Fuel Program (NSNFP) and the Independent Spent Fuel Storage Installations (ISFSI) under Nuclear Regulatory Commission license granted to the U.S. Department of Energy (DOE). The analysis performed meets the requirements set forth in Section 16.2.6, "Quality Trending" of DOE/RW-0333P, *Quality Assurance Requirements and Description* (QARD). The trend analysis was performed in accordance with NSNFP Quality Assurance Staff Procedure QAS 16.03 and ISFSI Procedure IQP 16.03. The data analyzed is categorized into four groups: NSNFP, Spent Nuclear Fuel (SNF) Sites, NSNFP suppliers and ISFSIs.

1.2 Description of Trending Process and Methodology

Deficiencies are categorized as conditions adverse to quality and significant conditions adverse to quality, and are documented as a Deficiency Report (DR) or Corrective Action Request (CAR) respectively. DR/CAR reports are assigned subject codes and direct cause codes. Significant conditions adverse to quality documented as CAR reports are additionally assigned a root cause code, based on formal root cause analysis. Codes are recorded in the NSNFP Quality Assurance (QA) Corrective Action Tracking Trending System (CATTS) to facilitate analysis. The codes are sorted into four groups, the NSNFP, SNF Sites, NSNFP suppliers and ISFSIs to facilitate analysis by calendar year. Other sources of information are also used for analysis to identify trends adverse to quality. Previous NSNFP QA trend analysis reports are used in analyses.

Subject codes reflect the primary QARD requirement violated that defines the basis of a DR/CAR. Direct cause codes are the apparent cause of a condition adverse to quality. Root cause codes reflect the identified root cause that results from formal analysis. The first two codes, subject and direct cause, are subjective, and are validated by review of the DR/CAR reports during analysis. Root cause codes reflect the results of formal analysis and do not require validation.

Subject codes, direct cause codes, and root cause codes are used to compare the frequency of occurrence of like deficiencies. Codes are sorted by organization for each calendar year to identify an increase in the frequency of occurrence over time. Where an increase in frequency is identified, each individual DR/CAR is evaluated to validate that common issues are identified, and that an adverse trend may be present.

Subject codes, direct cause codes, and root cause codes are evaluated by Pareto analysis for each organization. This analysis identifies the most frequent occurrence of a deficiency code. DR/CAR reports are evaluated for the highest occurrence of a code to validate that common issues are identified. The highest occurrence of a code that reflects a common issue may represent an indicator of an adverse trend.

The DR/CAR reports are evaluated for timeliness of corrective action, including (as applicable) a discussion of ineffective or overdue corrective actions for each organization. The duration of closed and open DR/CAR reports are compared by calendar year to determine if an adverse trend in timeliness of corrective action is present.

Potential adverse trends are evaluated against the criteria for trends adverse to quality in procedure QAS 16.03 "Quality Assurance Trending" (IQP-16.03 for ISFSI analysis). If the analysis finds the trend to be adverse to quality, then a review of open and recently completed correction actions is performed to determine whether mitigating actions are in process that may resolve the adverse trend. If there are no mitigating actions, then an evaluation of the trend for a significant condition adverse to quality is performed to determine whether a CAR will be issued to the responsible organization.

The discussion for each organization includes a description of documentation used as a part of the analysis, graphs of selected subject and direct cause codes, and conclusions regarding trends adverse to quality. Attachment B provides graphs and tables that summarize the subject codes, direct cause codes, root cause codes, and the average duration of open and closed DR/CAR reports for the organizations analyzed. Attachments C and D provide a list of subject codes and direct/root cause codes respectively. Administrative controls that may address adverse trends, lack of timely corrective action, or indicators for adverse trends are discussed. Conclusions that require action by management are identified under the Executive Summary and Results.

2. ANALYSIS

2.1 National Spent Nuclear Fuel Program

The NSNFP is comprised of a Quality Assurance organization and a Project Support Organization (PSO). Deficiency reports are assigned to each organization recognizing unique responsibilities, however, the analysis evaluated the data as representative of one organization.

2.1.1 Subject Codes

The evaluation of subject codes for the NSNFP indicates an overall improvement in QA program implementation and a decline in specific QA program criteria from 1999 through 2001. An overview of the frequency of occurrence for subject codes indicates two categories of increased frequency for subject codes B.01.2 and E.01. These indicators contrast to thirteen general subject code categories where overall frequencies remained the same or decreased from the previous two years evaluated (see Attachment B). Improvement is present under subject code "B.12.1.2, Ensure personnel are indoctrinated and trained," and code "Q.02.2, Individuals creating QA records shall ensure the QA records are legible, accurate and complete".

The frequency of occurrence of deficiencies under subject code "B.1.2, Quality Assurance Program Documents", have increased from one in 1999, two in 2000 to three in 2001. The DRs address the following deficiencies:

- Deficiency 99-NSNF-AU-125-004, code B.01.2.3, addresses a failure to provide positive controls over external interfaces in statements of work.

- Deficiency 00-RW-08/31/00-DR-002 code B.01.2.4, addresses that Memorandums of Agreement did not require implementing organizations to use the latest revision of the QARD.

- Deficiency 00-NSNF-AU-011-DR-002, code B.01.2, addresses performing quality affecting work without approved NSNFP procedures.

- Deficiency 01-NSNFP-AU-001-DR-002, code B.01.2.1, addresses Quality Assurance Management Plan DOE/SNF-QMP-001 as outdated in reflecting NSNFP roles, responsibilities, organization interfaces, and the organization structure.

- Deficiency 01-QAMA-9/18-DR-001, code B.01.2.1, stated: "The NSNFP procedure system (hierarchy, structure, and processes) should be evaluated in the areas noted in this section to determine where improvements could be made. Management should commit to a continuing program that provides for a systematic improvement of the procedure system."

- Deficiency 01-QAMA-9/18-DR-002, code B.01.2.2, stated: "DOE should ensure that an effective quality engineering function is established within the NSNFP contractor organization. The role of this function should be to work with line management to ensure that quality is built into all products and processes. The function should be established with a focus on finding and correcting problems in process. The function should also be coordinated with QA to ensure that a proper balance between prevention activities and appraisal activities is achieved."

The subject codes for the listed DRs under subject codes B.1.2 do not reflect a repeat of the same deficiency or an increasing frequency of the same deficiency, and do not indicate a trend adverse to quality.

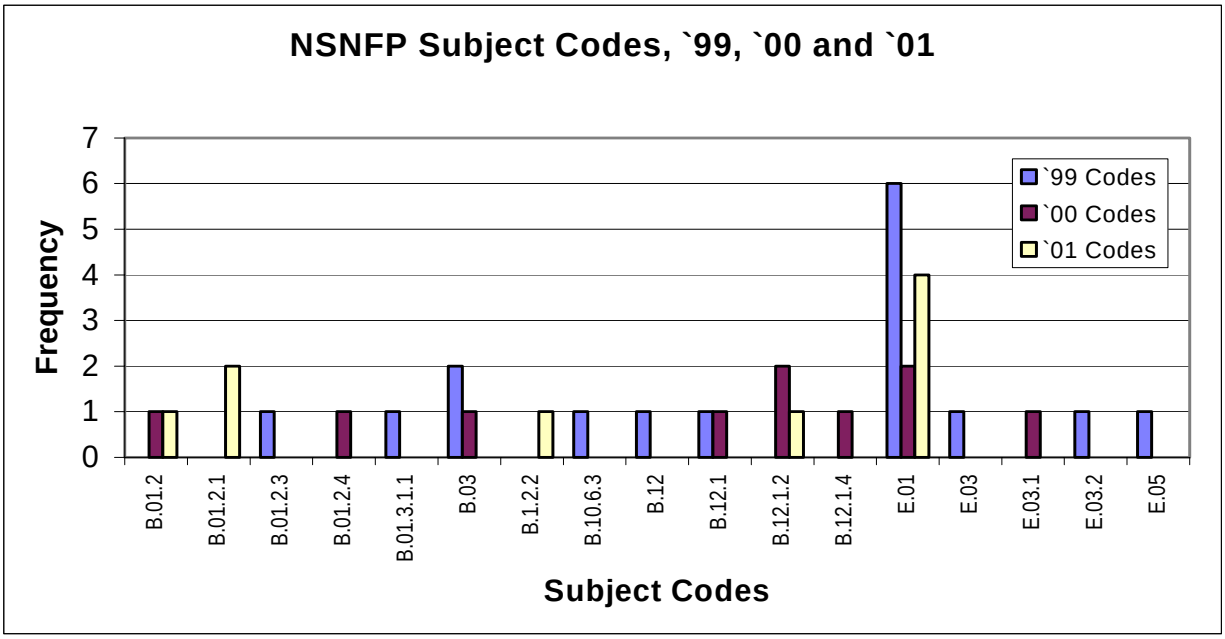


Figure 1. NSNFP Subject Codes for QARD Section 2, "Quality Assurance Program" and Section 5, "Implementing Documents" for 1999, 2000 and 2001.

The frequency of occurrence of subjects under the criteria of "E.01, Work shall be performed in accordance with controlled implementing documents" decreased from six in 1999 to two in 2000. However, the number increased to four in 2001. The DRs for 2001 address the following deficiencies:

- Deficiency 01-NSNF-S-006-DR-003, addresses that "there was no objective evidence that CDAs (deficiencies corrected during the audit) were verified complete or transmitted to quality records as required by these PMPs (Program Management Procedures)".

- Deficiency 01-NSNFP-AU-001-DR-003 addressed that "expedited changes are not incorporated into the procedures per the requirements of the PMP."

- Deficiency 01-NSNFP-AU-001-DR-004 stated "Statement of Work DOE/SNF/PP-024 lists EP (engineering procedures) procedures for the performance of quality affecting work. The EP procedures are not reflected by the QARD Requirements Matrix as implementing procedures."

- Deficiency 01-NSNFP-AU-001-DR-007 stated: The NSNFP is not fully implementing approved procedures for the performance of quality affecting work."

The deficiencies for 2001 reflect the same code, E.01, and reflect an increased frequency of a failure to perform work to approved implementing procedures. This repeated failure is addressed in the NSNFP internal audit 01-AU-001. Deficiency Report 01-NSNFP-AU-001-DR-007 states: "The NSNFP is not fully implementing approved procedures for the performance of quality affecting work." Corrective actions to address this DR and deficiency 01-QAMA-9/18-DR-001 have resulted in the revision of procedures to improve usability and training of the NSNFP staff to the new procedures. These actions were evaluated and are viewed as adequate to address the emergent trend adverse to quality. No further action is required by this report.

Pareto analysis of subject codes for 2001 does indicate an adverse trend under subject code E.01, however, actions discussed in the preceding paragraph adequately address the adverse trend.

2.1.2 Direct Cause Codes

The evaluation of direct cause codes for the NSNFP indicates an overall improvement in QA program implementation and a decline in specific attributes of the QA program from 1999 through 2001. An overview of the frequency of occurrence for direct cause codes indicate two categories of increased frequency for the NSNFP, direct cause codes 01 B g(4) and 02 A d. These indicators contrast to 20 direct cause codes where overall frequencies remained the same or decreased from the previous two years evaluated (see Attachment B). Improvement under the direct cause code of "3 A d, Standards, Policies, Administrative Controls recently changed" is reflected with a decline from eleven in 2000 to zero in 2001. Improvement under the basic code "1 B, Inadequate/wrong procedure" is reflected with a decline from thirteen in 2000 to three in 2001. However, under the specific code "1 B g(4), Procedure does not describe how the requirement will be implemented" there was a minor increase over 2001.

Deficiency reports with the assigned direct cause code "02 A d, Procedure not used, or used improperly" have increased in frequency from zero during 2000 to ten in 2001. A review of the individual DRs with code "02 A" reflect a common direct cause of not following procedures. This repeated failure is specifically addressed in NSNFP internal audit 01-AU-001. Deficiency report 01-NSNFP-AU-001-DR-007 states: "The NSNFP is not fully implementing approved procedures for the performance of quality affecting work." This deficiency report sited six DRs and two deficiencies corrected during the audit as having a common direct cause of personnel not using procedures. Corrective actions for this DR and deficiency 01-QAMA-9/18-DR-001 001 have resulted in the revision of procedures to improve usability and training of the NSNFP staff to the revised NSNFP procedures. Effectiveness of corrective action will be evaluated as a part of the FY 02 internal audit. These actions are viewed as adequate to address the trend adverse to quality. No additional action is required by this report for this adverse trend.

Reviews of the DRs identified with code "01 B g (4)" reflect instances where procedures do not describe how requirements will be implemented. This code has increased by a frequency of one for each year that data is available, and reflects an adverse trend. Corrective actions implemented in response to

DR 01-QAMA-9/18-DR-001 address this adverse trend. The effectiveness of the revised procedures will be evaluated by the NSNFP FY 02 internal audit. No further action is required by this report.

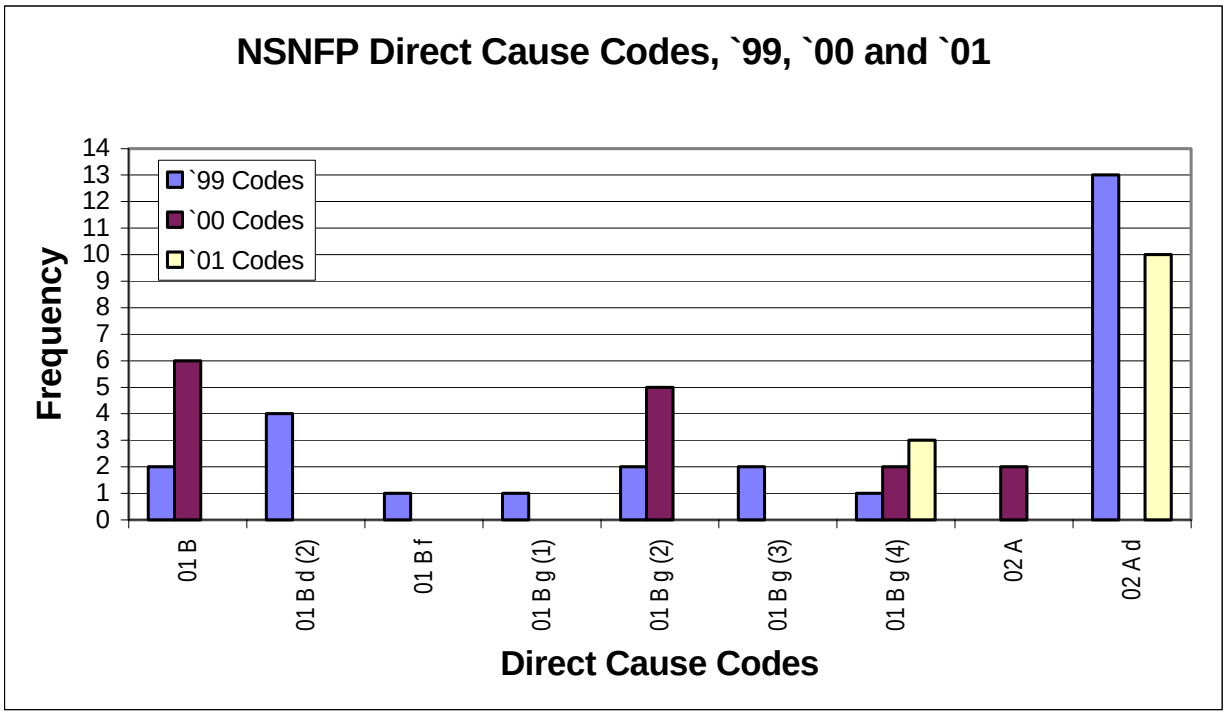


Figure 2. NSNFP Direct Cause Codes for Category "01 B, Inadequate/wrong procedure", and 02 A, "Personnel-Human Performance, Lack of attention to a task" for 1999, 2000 and 2001.

Pareto analysis of direct cause codes indicates and adverse trend for code 02 A d. However as discussed under paragraph 2.1.2, corrective actions are in process of implementation for DR report 01-NSNFP-AU-001-DR-007. These corrective actions are found to be adequate to address the adverse trend. No further action is required by this report.

2.1.3 Root Cause Codes

No significant conditions adverse to quality were identified during 2001, resulting in no assignment of root cause codes. This positive trend continues from 2000, when no significant conditions adverse to quality were found. No adverse trends are identified from this analysis.

2.2 Spent Nuclear Fuel Sites

Spent Nuclear Fuel sites are comprised of Hanford, Idaho National Engineering Environmental Laboratory (INEEL), Oak Ridge National Laboratory (ORNL), and the Savannah River Site (SRS). The analysis is performed for the individual sites.

The basis of analysis is limited to the results of audits and surveillances performed by NSNFP QA. However, a reduction in the budget of the NSNFP QA Program reduced the schedule of surveillance performed of SNF sites, reducing the available data for analysis of performance.

2.2.1 Hanford

The evaluation of deficiency codes of the Hanford SNF program found continued satisfactory performance, as reflected by the results of audits and surveillances. 1999 resulted in the identification of 22 deficiencies, whereas only one deficiency was identified in 2000. This improved level of performance continued with only two adverse conditions corrected during the annual audit in 2001. The effective performance of the Hanford SNF organization has prevented the occurrence of trends adverse to quality for 2001.

A comparison of subject codes and root-cause codes for 1999, 2000, and 2001 found no common code and no increase in frequency of the occurrence of a code. No adverse trends are identified by the evaluation of subject codes and root cause codes.

A comparison of direct cause codes for 1999 and 2000 found one instance of a common code, however, there was no repeat of any code in 2001. No adverse trends are identified by the evaluation of direct cause codes.

Pareto analysis of subject codes, direct cause codes, and root cause codes for 2001 does not provide an indicator of adverse trends.

2.2.2 INEEL

The INEEL SNF program was last evaluated by audit in 1998. Deficiencies were identified in the majority of the elements of the INEEL SNF QA program. Subsequent to that audit, INEEL SNF has developed a new program description. A qualification audit, scheduled for 2001, has been re-scheduled for 2002. Annual deficiency data is not available for analysis, therefore, no analysis for trends adverse to quality is performed for this report.

2.2.3 ORNL

The evaluation of deficiency codes for the ORNL SNF QA program found continued satisfactory performance in 2001. One DR was issued in 1998, two DRs were issued in 2000, and NSNFP Surveillance 01-ORNL-S-002, conducted in March of 2001 identified no deficiencies or concerns.

The low level of activity on SNF work at ORNL has resulted in the delay of the NSNFP annual audit. The scope of this audit was intended to be a closeout audit at ORNL, as all NSNFP related activities are to be completed.

There are no adverse trends identified at ORNL for this report.

2.2.4 SRS

The annual audit of SRS was delayed within the fiscal year, resulting in trend data not being available within the calendar year of 2001. This delay is due in part to funding issues at SRS that will result in the demobilization of the melt dilute process of spent nuclear fuel at SRS. Additionally, reduced funding for the NSNFP QA program resulted in a reduction in surveillances of SRS SNF activities. The lack of audit and surveillance results precludes performing an analysis of the performance of SRS for implementation of the NSNFP approved QA program. However, it should be noted that the Corrective Action Request, 01-SRS-02/22-01-CAR-001, issued as a result of last years NSNFP trend analysis has

not been satisfactorily resolved by SRS. The failure of SRS to provide timely corrective action to the significant condition adverse to quality has been addressed by SRS management and NSNFP QA through telephone conferences, and resolution is in process.

2.3 National Spent Nuclear Fuel Program Suppliers

The SNF suppliers currently approved to provide items and services to the NSNFP are Argonne National Laboratory-East (ANL-E), Argonne National Laboratory-West (ANL-W), Battelle Pacific Northwest National Laboratory (Battelle PNNL), JMI Inc., and Lockheed Martin Energy Systems-Oak Ridge-Y12 (LMES-OR-Y12). Audits for the suppliers are performed triennially. Surveillances are also performed to monitor supplier performance. One supplier audit was conducted during calendar year 2001 (JMI). However, NSNFP budget reductions have precluded the performance of on-site supplier surveillance for FY 2001, and no data is available to support evaluations for trends.

2.3.1 Argonne National Laboratory-East

ANL-E-Chemical Technology Division was evaluated in 1999 by audit 1999-NSNF-AU-039, with subsequent evaluation performed under surveillance 00-SUPP-S-003. The 1999 audit identified four DRs. Surveillance was conducted in 2000 to evaluate the effectiveness of the ANL-E QA program. No deficiencies were identified by the surveillance. The next audit of ANL-E is scheduled for March of 2002. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report.

2.3.2 Argonne National Laboratory-West

ANL-W was evaluated in 1999 by audit 1999-NSNF-AU-058, with a subsequent evaluation performed in 2000 under surveillance 00-SUPP-S-005. The 1999 audit identified six DRs. The surveillance conducted in 2000 identified one DR, 00-ANLW-S-005-DR-001. No surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this analysis.

2.3.3 Battelle-Pacific Northwest National Laboratory

Battelle-Pacific Northwest National Laboratory (PNNL) was evaluated in 1999 by audit 1999-NSNF-AU-036, with a subsequent evaluation performed in 2000 under surveillance 00-SUPP-S-002. The 1999 audit identified four DRs. No deficiencies were identified by the surveillance. No NSNFP QA audit or surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this analysis.

2.3.4 JMI Inc.

The tri-annual audit of JMI Inc. was conducted during 2001. Two deficiencies were identified as a result of this audit.

The subject code for one DR reflected a repeat of one code from the 1999 surveillance, code “E.01, Work shall be performed in accordance with controlled implementing documents.” The repeat of the code does not represent a trend adverse to quality.

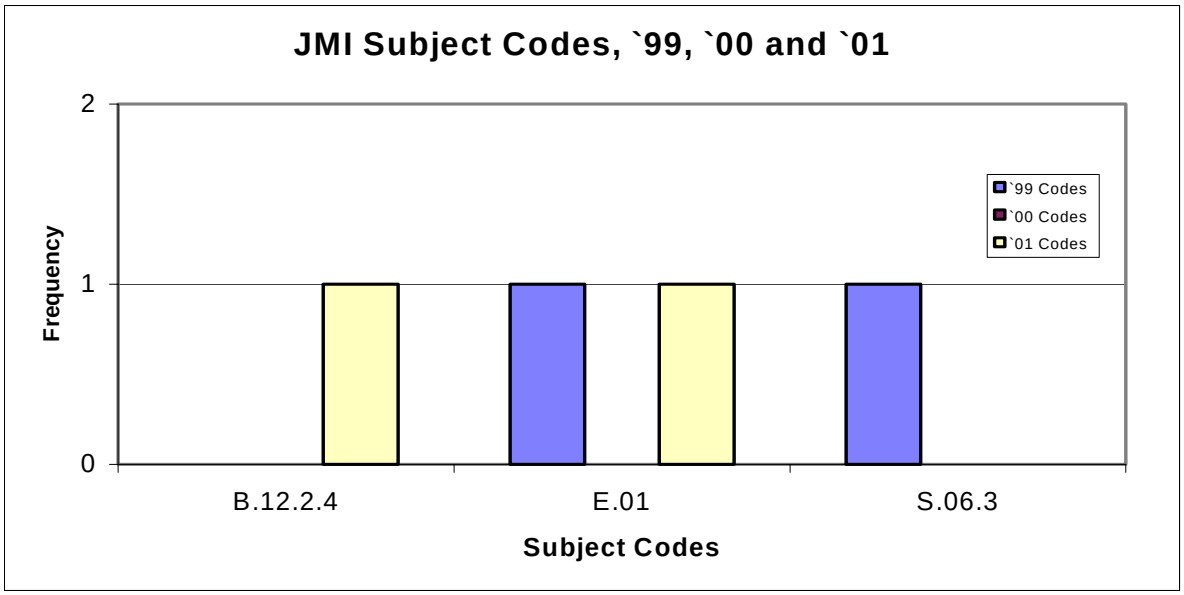


Figure 4. JMI Inc. Subject Codes identified for 1999, 2000 and 2001.

Direct cause codes for the two deficiencies from 2001 do not reflect a repeat from the 1999 surveillance. Although the general direct cause code for deficiency 01-JMI-AU-004-CDA-001 was "02 A, Lack of attention to a task", the deficiency does not represent an increase in frequency and does not indicate a trend adverse to quality.

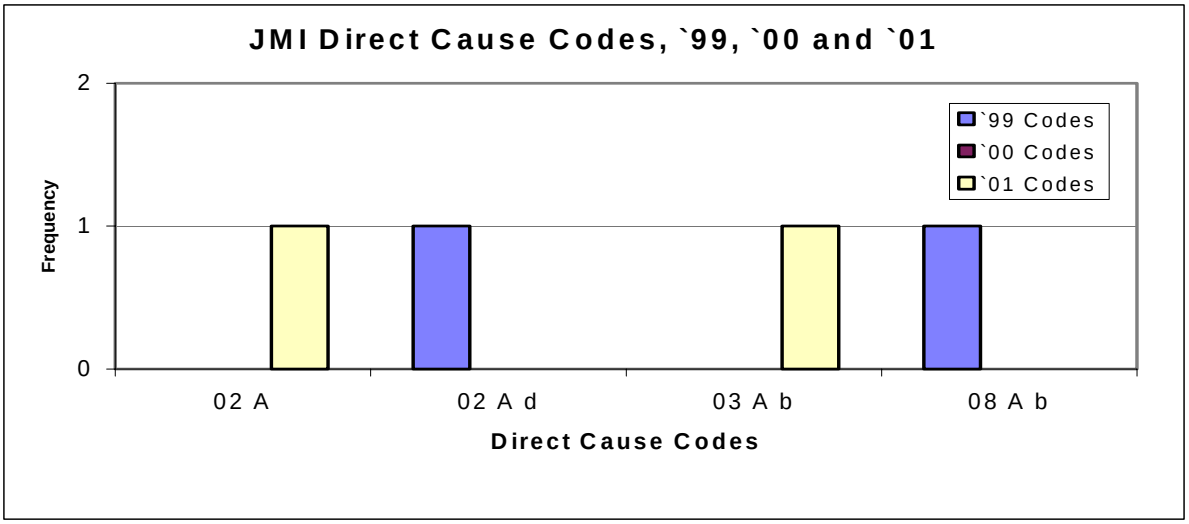


Figure 5. JMI Inc. Direct Cause Codes identified for 1999, 2000 and 2001.

No significant conditions adverse to quality were identified and no evaluation of root cause codes is performed. No trends adverse to quality are identified for JMI Inc. as a result of this report.

2.3.5 Lockheed Martin Energy Systems-Oak Ridge-Y12

The last audit of LMES-OR-Y12, 1999-NSNF-AU-035, was performed in December 1998. Audit 1999-NSNF-AU-035 identified seven deficiencies that were corrected prior to approval of the LMES-OR-Y12 QA program. The NSNFP QA audit scheduled for 2001 was postponed to 2002. No NSNFP QA audit or surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this analysis.

2.4 Independent Spent Fuel Storage Installations

The ISFSI program include two licensed facilities, Three Mile Island 2 (TMI-2) and Fort Saint Vrain (FSV). The analysis for trends adverse to quality for the report issued for the calendar year 2000 was confounded by a change in the management structure between 1999 and 2000; in 1999, the two facilities were treated as separate organizations. Oversight focused on the individual facility organizations. For 2000, management of these facilities was consolidated, changing the scope of oversight to examine, in part, the separate facilities and the common management organization. For this report, the analysis will evaluate the two facilities as a single organization.

2.4.1 Subject Codes

Subject codes reflect an overall improvement in QA program implementation for the DOE-ID ISFSIs. An overview of the frequency of occurrence for subject codes indicate two categories of increased frequency for the DOE-ID ISFSIs, subject codes “E.05, Compliance with Implementing Documents” and category “Q.05.2, Quality Assurance Records, Storage Methods shall be developed”. These indicators contrast to fourteen general subject code categories where overall frequencies remained the same or decreased from the previous two years evaluated (see Attachment B).

Under the general subject code “E, Implementing Documents”, the increase of code “E.05” contrasts to the reduction of deficiencies related to “E.01, Work shall be performed to implementing documents”. Although these subject codes are closely related, the frequency of codes under “E.01” was ten in calendar year 1999, four in 2000, and zero in 2001. The frequency of “E.05” was two in 2001. The two deficiencies with subject code “E.05”, Deficiency Reports 01-ISFSI-S-002-DR-001 (BBWI, TMI) and 01-NSNF-QA-04-DR-001 (DOE-ID, FSV) were found in different support organizations for different facilities. The increase in the frequency of code “E.05” does not represent a trend adverse to quality.

Under the subject of Quality Assurance Records, the frequency of code “Q.05.2, Storage Methods shall be developed to preclude deterioration of QA records” increased from zero to three. The DRs address the following deficiencies:

> 02-ISFSI-S-006-DR-001, states in part: “MCP-3045, "NRC Operations Records Management" does not include requirements for the creating and the maintenance of electronic records as required by NRC recommended NIRMA guidelines. MCP-3045, "NRC Operations Records Management" does not describe the process of transferring QA records from FSV.”
>
> 02-ISFSI-S-006-DR-002, states in part: “MCP-557, "Managing Records," does not include requirements for the creating and the maintenance of electronic records as required by NRC recommended NIRMA guidelines.”
>
> 01-ISFSI-AU-011-CDA-002, states in part: “Contrary to the above, numerous in process QA records were not stored in fireproof cabinets.”

The two DRs, 02-ISFSI-S-006-DR-001 and 002 were written during the same surveillance to address a single deficiency that resided in procedures for two different organizations. The deficiency corrected during the surveillance, 01-ISFSI-AU-011-CDA-002, addressed an issue that differed from the deficiency reports. The increase in frequency for this subject code does not indicate a trend adverse to quality.

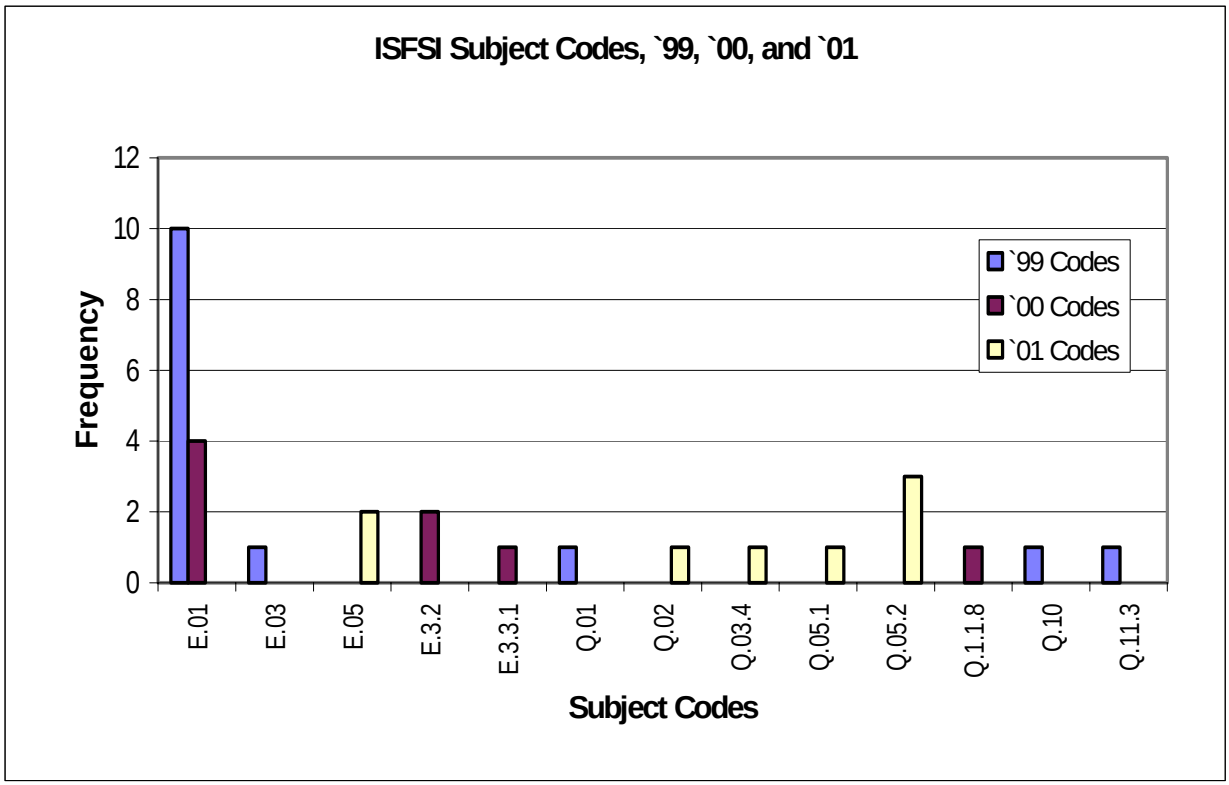


Figure 6. ISFSI Subject Codes for "E, Implementing Documents" and ", Q, Quality Assurance Records" for 1999, 2000 and 2001.

Pareto analysis of subject codes for 2001 focused on code E.05.2. As stated above, two of the DRs assigned the subject code were written during the same surveillance to address a single deficiency that resided in procedures for two different organizations, and the deficiency corrected during the surveillance does not indicate a repeat of the same deficiency. Pareto analysis of subject codes for 2001 does not indicate an adverse trend under subject code Q.05.2.

2.4.2 Direct Cause Codes

The evaluation of direct cause codes for the DOE-ID ISFSIs indicates an overall improvement and decline in performance from 1999 through 2001. An overview of the frequency of occurrence for direct cause codes indicate two categories of increased frequency for the DOE-ID ISFSIs, direct cause codes 01 B d(2) and 02 A b. These indicators contrast to 24 direct cause codes (that occurred from 1999 through 2001) where overall frequencies remained the same or decreased from the previous two years evaluated (see Attachment B).

The frequency of occurrence of deficiencies under direct cause code "02 A b, Personnel-Human Performance, lack of attention to task, oversight", increased from zero in 1999, five in 2000 to six in 2001. This contrasts to improvement under the direct cause code of "02 A d, Procedures not used, or used

improperly" with a decline from twenty-one in 1999, eleven in 2000, and two in 2001. The DRs issued in 2001 under code 02 A b address the following deficiencies:

> Deficiency 01-ISFSI-S-002-DR-001 states: "A review of the completed procedures "TPR-6283 and TPR-6282" showed that steps marked "N/A" are not being initialed or dated and are not consistently being justified on the comment sheets for these procedures."
>
> Deficiency 01-NSNF-QA-04-DR-001 states "NSNF QAPM no longer performs the functions as described in the FSV and TMI-2 SARs; these duties now lie with the DOE-ID Quality Assurance Manager."
>
> Deficiency 01-ISFSI-AU-011-DR-002 states "Review criteria is not being utilized when necessary for procedure changes effecting the implementing procedure associated with the licensed facilities."
>
> Deficiency 01-ISFSI-AU-011-DR-003 states "Mandatory comments are not being documented for procedure changes associated with the ISFSIs."
>
> Deficiency 01-ISFSI-AU-011-CDA-001 states "Inspection of bulletin boards in numerous buildings at INTEC revealed that in no case was adequate and accurate information made available to employees who may wish to participate in the DOE-Idaho or INEEL M&O contractor's employee concerns programs. In some cases, no information was provided to building occupants, while in other cases, inaccurate contact names and phone numbers for the ECPs were provided.
>
> Deficiency 01-ISFSI-AU-011-CDA-002 states "Contrary to the above, numerous in process QA records were not stored in fireproof cabinets."

The deficiencies listed above reflect a common direct cause code "02 A b". Code "02 A b" represents 40% of the deficiencies identified during 2001. However, the deficiencies occurred in three different organizations. Of the deficiencies occurring within a single organization, only two of the deficiencies reflect a recurrence of a deficiency in a single process. Based on the criteria of ISFSI procedure IQP-16.03, the recurrence of code "02 A b" does not meet the criteria of a trend adverse to quality. However, ISFSI management should evaluate or monitor personnel performance to assure a trend adverse to quality does not develop over the next calendar year.

The frequency of occurrence of deficiencies under direct cause code "01 B d(2), Inadequate/wrong procedure, Requirements not covered/addressed", have increased from one in 1999, two in 2000 to four in 2001. The DRs issued in 2001 address the following deficiencies:

> Deficiency 02-ISFSI-S-006-DR-001 states "MCP-3045, "NRC Operations Records Management" does not include requirements for the creating and the maintenance of electronic records as required by NRC recommended NIRMA guidelines. MCP-3045, "NRC Operations Records Management" does not describe the process of transferring QA records from FSV."
>
> Deficiency 02-ISFSI-S-006-DR-002 states "MCP-557, "Managing Records," does not include requirements for the creating and the maintenance of electronic records as required by NRC recommended NIRMA guidelines."
>
> Deficiency 01-INEEL-S-005-DR-002 states" Not all personnel have completed the required training identified for the NRC Licensed Facilities. Personnel have not been assigned to all job codes identified for the the NRC Licensed Facilities (FSV and TMI-2)."

Deficiency 02-ISFSI-S-001-DR-002 states" The implementing procedures MCP-135 and MCP-9395 do not clearly identify what is a QA record or how to process the records associated with controlled document change packages."

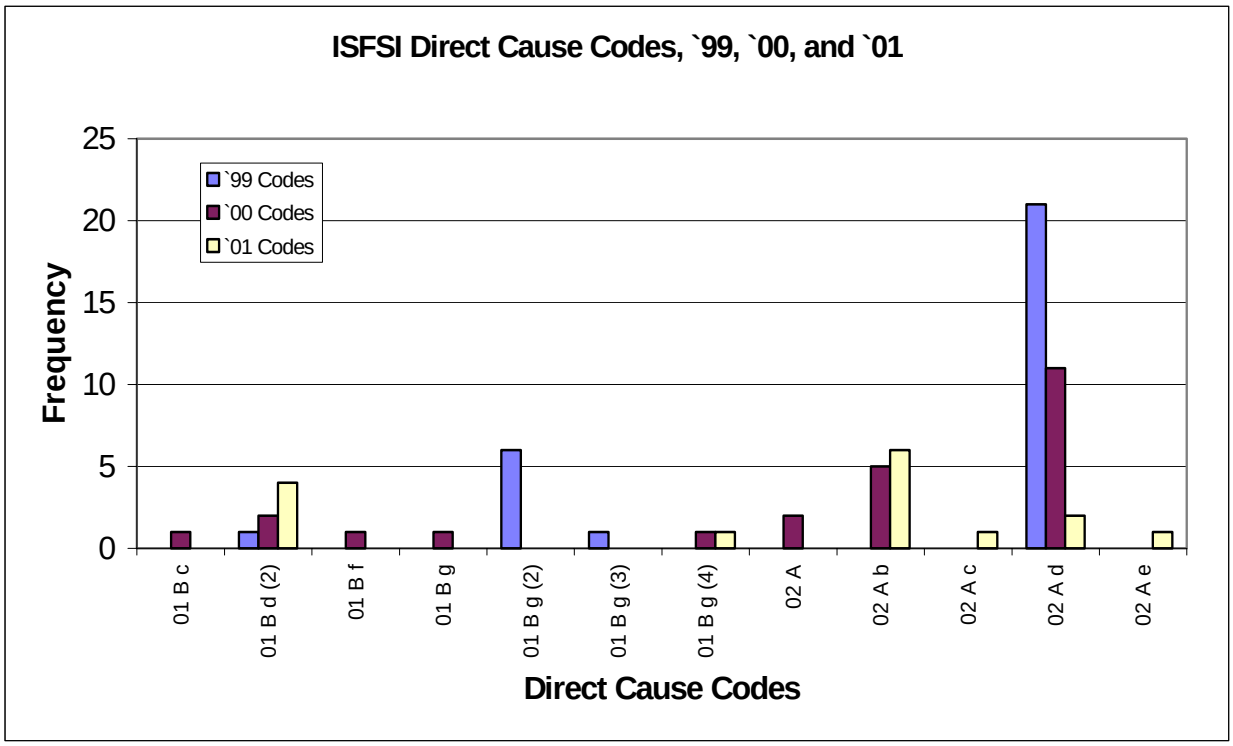


Figure 7. ISFSI Direct Cause Codes for "01, Inadequate/Wrong Procedure" and "02, Personnel-Human Performance" for 1999, 2000 and 2001.

Although the direct cause codes for these four deficiencies are common, the first two deficiencies resulted from the application of new criteria to be applied to the DOE-ID ISFSIs, specifically NRC recommended Nuclear Information and Records Management Association guidelines. As the application of these guidelines is new for the DOE-ID ISFSIs, the deficiencies are not considered as a valid contribution to the development of an adverse trend to quality. Reviewing the remaining two deficiencies do not represent a trend adverse to quality.

Pareto analysis of direct cause codes for 2001 focused on code "02 A b". As stated above, the deficiencies reflect a common direct cause code. Code "02 A b" represents 40% of the deficiencies identified during 2001. However, as discussed above under direct cause code "02 A b" the deficiencies occurred in three different organizations. Of the deficiencies occurring within a single organization, only two of the deficiencies reflect a recurrence of a deficiency in a single process. Based on the criteria of ISFSI procedure IQP-16.03, the recurrence of code "02 A b" does not meet the criteria of a trend adverse to quality. However, ISFSI management should evaluate or monitor personnel performance to assure a trend adverse to quality does not develop over the next calendar year.

2.4.3 Root Cause Codes

The evaluation of root cause codes found a reduction in the general frequency of these codes due to a reduction in the number of significant conditions adverse to quality identified at the ISFSIs. Eleven CARs were issued in 2000, and only one was issued in 2001. The root cause code assigned for the 2001

CAR was not a repeat from 2000. The single occurrence of the root cause does not define an adverse trend from Pareto analysis. No adverse trend to quality is identified for root cause codes for 2001.

3. CORRECTIVE ACTION TIMELINESS

The DR/CAR reports were evaluated for timeliness of corrective action. Data for individual organizations, SNF sites, and suppliers were evaluated by calendar year to determine if an adverse trend in timeliness of corrective action is present. However, the data available for some organizations does not fully support this type of comparison, since data for NSNFP suppliers and INEEL SNF is only available for one year. January 2, 2002 is the reference date for the open/closed status of individual DR/CAR reports. This date is also used to calculate the duration of open DR/CAR reports.

Overall performance of all the SNF programs has improved in providing timely corrective action. The NSNFP QA organization tracks and reports on a BI-weekly basis a summary report of all open deficiency reports. During calendar year 2001, the number and average duration that deficiency reports are open has dropped. A significant reduction in the number of open deficiency reports is pending within the NSNFP that reduces even further, the average duration and number of open deficiency reports.

3.1 National Spent Nuclear Fuel Program

The NSNFP is comprised by of the PSO and QA organization. The two groups work to the same program management procedures. However, data was sorted to evaluate the individual organization duration. The NSNFP PSO and QA organizations have open and closed DR/CAR reports for both 2000 and 2001. The NSNFP PSO has one deficiency report open from 1999, and NSNFP QA does not have any deficiencies open from 1999.

	NSNFP QA		NSNFP PSO	
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA	1	812
Closed `99	15	260.5	17	329.4
Open `00	1	541	6	526.1
Closed `00	5	176.4	18	217.7
Open `01	3	106	8	216.8
Closed `01	2	48.5	3	21.3

Table 1. Average number of days that DR/CAR reports are open as of 1/01/02, for open and closed reports issued in 1999, 2000, and 2001 for NSNFP PSO and QA.

Although the NSNFP PSO and QA organizations own the oldest deficiencies of all the programs tracked by NSNFP QA, the organizations have just completed long term corrective actions that will result in the closure of fourteen deficiency reports. These closures will reduce the backlog of open deficiency reports and greatly reduce the average duration the deficiency reports are open. Additionally, the NSNFP QA organization has been tracking through BI-weekly reports, the status of open deficiency reports. Delinquency reports are issued when due dates are exceeded. These two actions are viewed as adequately

addressing the backlog and duration of open deficiencies identified in the 1/1/02 report of open items used for this analysis. The NSNFP QA organization continues to monitor the duration of open deficiency reports in external and internal organizations as a part of the NSNFP corrective action program. No adverse trend to quality is identified by this evaluation.

Date of Status Report of Open DRs/CARs	Average No. of Days Open	Number of Open DRs/CARs
01/26/01	309.8	84
01/01/02	259	33

Table 2. Listing of status reports of the average number of days for all DR/CAR reports tracked by NSNFP QA and the number of open DR/CAR reports to reflect increased management of corrective actions by NSNFP.

3.2 Spent Nuclear Fuel Sites

The SNF sites are Hanford, INEEL, ORNL, and SRS. Data was sorted to evaluate the individual organization duration.

3.2.1 Hanford

The Hanford SNF organization has no DR/CAR reports open. In 2001, only two deficiencies were identified within the Hanford SNF program. Both of the deficiencies were corrected during the NSNFP QA audit. This level of performance reflects continued improvement by the Hanford SNF program during 2001. No adverse trends are identified related to the Hanford SNF program.

3.2.2 INEEL

The INEEL SNF Program was last audited in 1998. This audit resulted in deficiencies addressing a major part of the INEEL SNF QA Program. In the 2000 NSNFP QA Annual Trending Report, the INEEL-SNF Program was identified as owning the longest duration of open DR/CAR reports. All of the deficiencies opened in 1998 were closed during 2001. There is one open deficiency report opened in 2001, 01-INEEL-S-005-DR-001. The duration of this DR is 245 days. However, INEEL management as part of an effort to bring the INEEL SNF program into compliance with DOE/RW-0333P to pass an NSNFP QA qualification audit is addressing this deficiency. No further action is requested by this report.

3.2.3 ORNL

The evaluation of deficiency report duration for the ORNL SNF program found satisfactory performance for both 1998 and 2000. No audit or surveillance was conducted during 2001. The low number of deficiencies does not indicate an adverse trend, and individual duration history reflects satisfactory performance. The single DR issued in 1998 was open for 281 days, whereas the two deficiencies identified during the 2000 audit were corrected during the audit. The extended duration for the DR issued in 1998 was in part due to coordinating the NSNFP QA schedule for verification of corrective action. No further action is requested by this report.

3.2.4 SRS

The evaluation of durations of DR/CAR reports for SRS SNF found satisfactory performance for 1999 and a reduction in the duration for closed DRs issued in 2000. The average duration for 1999 was 262 days for 12 DR/CAR reports. The average duration for closed deficiencies for 2000 was 235 days for eleven DRs. However, there remain open two DRs from 2000, duration 419 days, and one CAR issued in 2001, open for 300 days. These deficiency reports were the subject of two conference calls between NSNFP QA management and Westinghouse Savannah River Company QA management. Resolution of the deficiencies has been identified and is in process. Additionally, the extended duration for the DRs closed in 2000 and 2001 results in part from coordinating the NSNFP QA schedule for verification of corrective actions.

3.3 National Spent Nuclear Fuel Program Suppliers

The NSNFP suppliers are ANL-E, ANL-W, Battelle PNNL, JMI Inc., and LMES-OR-Y12. These SNF suppliers are not audited on an annual basis, which does not provide sufficient data to establish trends. However, average duration of deficiencies (all closed) issued to the SNF suppliers reflect satisfactory performance. The durations listed in Figure 10 for the DR/CAR reports was in part due to coordinating the NSNFP QA schedule for verification of corrective action. Deficiency reports are resolved prior to acceptance of items and services.

Organization-DR/CAR Status	Number of Deficiencies	Average Days Open
ANL-E Closed	4	209.5
ANL-W Closed	7	190
Battelle-PNNL Closed	4	116.3
LMES-OR-Y12 Closed	7	85
JMI Closed	2	224
JMI Inc. Open	1	88

Table 3. Average number of days that DR/CAR reports are open as of 1/01/02, for open and closed reports issued in 1999, 2000, and 2001 for NSNFP Suppliers.

3.4 Independent Spent Fuel Storage Installations

The analysis for timeliness of corrective actions is performed in the same manner as the analysis of cause codes. The two facilities, TMI-2 and FSV are evaluated as a single organization.

3.4.1 DOE-ID ISFSIs

The timelines of implementation of corrective action for calendar year 2001 at the ISFSIs has improved. The trend analysis report issued last year (2000) identified an adverse trend to quality for a lack of timely corrective actions at the ISFSIs. Corrective Action Request 01-INEEL-FSV/TMI-02/22/01-CAR-001 was issued to address this adverse trend. Corrective actions were implemented, verified, and the CAR was closed during calendar year 2001.

Corrective action duration for closed deficiencies in calendar year 1999 averaged 363 days, 2000 averaged 253 days, and there are no open deficiencies from either year 1999 or 2000. The average duration for closed deficiencies for 2001 is 91 days, and 74 days for open deficiencies. The duration for 2001 reflect an improvement in performance. No adverse trends are identified for timeliness of corrective action at the DOE-ID ISFSIs.

DOE-ID ISFSIs		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA
Closed `99	38	363.7
Open `00	0	NA
Closed `00	38	253
Open `01	10	74
Closed `01	8	91.3

Table 4. Average number of days that DR/CAR reports are open as of 1/01/02, for open and closed reports issued in 1999, 2000, and 2001 for the DOE-ID ISFSIs.

4. RESULTS

Data for the NSNFP, individual SNF sites, NSNFP suppliers and ISFSIs were analyzed to identify organization-specific adverse trends. Subject codes, direct cause codes, root cause codes, and corrective action durations were evaluated. The analysis of increases in frequency of codes, highest frequency of codes, and corrective action duration resulted in the identification of potential adverse trends in the NSNFP and QA, and ISFSI organizations. The analysis identified the following results.

NSNFP

Analysis of subject codes and direct cause codes for the NSNFP indicate an increasing frequency and high frequency of deficiencies related to not conducting work to approved procedures and procedures not used or used improperly. Additionally, direct cause codes indicate an adverse trend related to procedures not describing how requirements will be implemented. The increase in frequency and high frequency of occurrence represent a trend adverse to quality. However, this adverse trend has been addressed as a part of corrective action for Deficiency Report 01-NSNFP-AU-001-DR-007 and deficiency 01-QAMA-9/18-DR-001. Revised NSNFP procedures were issued with an effective date of 1/15/02, to improve usability of procedures. The NSNFP staff was trained to the new procedures prior to the effective date of the procedures. Effectiveness of the revised procedures will be evaluated as a part of the NSNFP QA internal audit for FY `02. No further action is requested by this report.

Hanford SNF

The evaluation of deficiency codes of the Hanford SNF program found continued satisfactory performance, as reflected by the results of audits and surveillances. No adverse trends were identified in the evaluation of subject codes, direct cause codes, root cause codes, or in the timelines of corrective action. No further action is requested by this report.

INEEL SNF

The INEEL SNF program was last evaluated by audit in 1998. Deficiencies addressing a major part of the INEEL SNF QA program were issued. Subsequent to that audit, INEEL SNF has developed a new program description. A qualification audit, scheduled for 2001, has been rescheduled for 2002. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report. No further action is requested by this report.

ORNL SNF

The evaluation of deficiency codes for the ORNL SNF QA program found continued satisfactory performance in 2001. One DR was issued in 1998, two DRs were issued in 2000, and NSNFP Surveillance 01-ORNL-S-002, conducted in March of 2001 identified no deficiencies or concerns. The low activity level at ORNL has resulted in the delay of the NSNFP annual audit. The scope of this audit was intended to be a closeout audit at ORNL, as all NSNFP related activities are to be completed. There are no adverse trends identified at ORNL for this report. No further action is requested by this report.

SRS SNF

The annual audit of SRS was delayed within the fiscal year, resulting in trend data not being available within the calendar year of 2001. This delay is due in part to funding issues at SRS that will result in the demobilization of the Melt Dilute process of spent nuclear fuel at SRS. Additionally, reduced funding for the NSNFP QA program resulted in a reduction in surveillance of SRS. The lack of audit and surveillance results precludes performing an analysis of the performance of SRS for implementation of the NSNFP approved SRS SNF QA program. However, it should be noted that the Corrective Action Request, 01-SRS-02/22-01-CAR-001, issued as a result of last years NSNFP trend analysis has not been satisfactorily resolved by SRS. The failure of SRS to provide timely corrective action to the significant condition adverse to quality has been addressed by SRS management and NSNFP QA through telephone conference and resolution is in process. No further action is requested by this report.

Argonne National Laboratory-East

ANL-E-Chemical Technology Division was evaluated in 1999 by audit 1999-NSNF-AU-039, with subsequent evaluation performed under surveillance 00-SUPP-S-003. The next audit of ANL-E is scheduled for March of 2002. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report. No further action is requested by this report.

Argonne National Laboratory-West

ANL-W was evaluated in 1999 by audit 1999-NSNF-AU-058, with a subsequent evaluation performed under surveillance 00-SUPP-S-005. No NSNFP QA audit or surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report. No further action is requested by this report.

Battelle-Pacific Northwest National Laboratory

Battelle-Pacific Northwest National Laboratory (PNNL) was evaluated in 1999 by audit 1999-NSNF-AU-036, with a subsequent evaluation performed under surveillance 00-SUPP-S-002. No NSNFP QA audit or surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report. No further action is requested by this report.

JMI Inc.

The tri-annual audit of JMI Inc. was conducted during 2001. Two deficiencies were identified as a result of this audit. The evaluation of subject codes and direct cause codes did not identify a trend adverse to quality. Review of timelines of corrective action did not identify a trend adverse to quality. No further action is requested by this report.

Lockheed Martin Energy Systems-Oak Ridge-Y12

The last audit of LMES-OR-Y12 was performed in December 1998. The audit scheduled for 2001 was postponed to 2002. No NSNFP QA audit or surveillance was conducted during calendar year 2001. Data is not available for analysis for calendar year 2001, therefore, no trends adverse to quality are identified by this report. No further action is requested by this report.

ISFSI

The evaluation of subject codes and root cause codes did not result in the identification of trends adverse to quality. The evaluation of direct cause codes identified an increase in frequency and highest frequency of occurrence under direct cause code “02 A b, Personnel-Human Performance, lack of attention to task, oversight”. Although analysis did not determine the repeated deficiencies represented a trend adverse to quality, ISFSI management should evaluate or monitor personnel performance to assure a trend adverse to quality does not develop over the next calendar year. No response is required to this request.

Timelines of corrective action improved during 2001. No trend adverse to quality is identified. No further action is requested by this report.

Attachment A

Supporting Documents

Supporting Documents

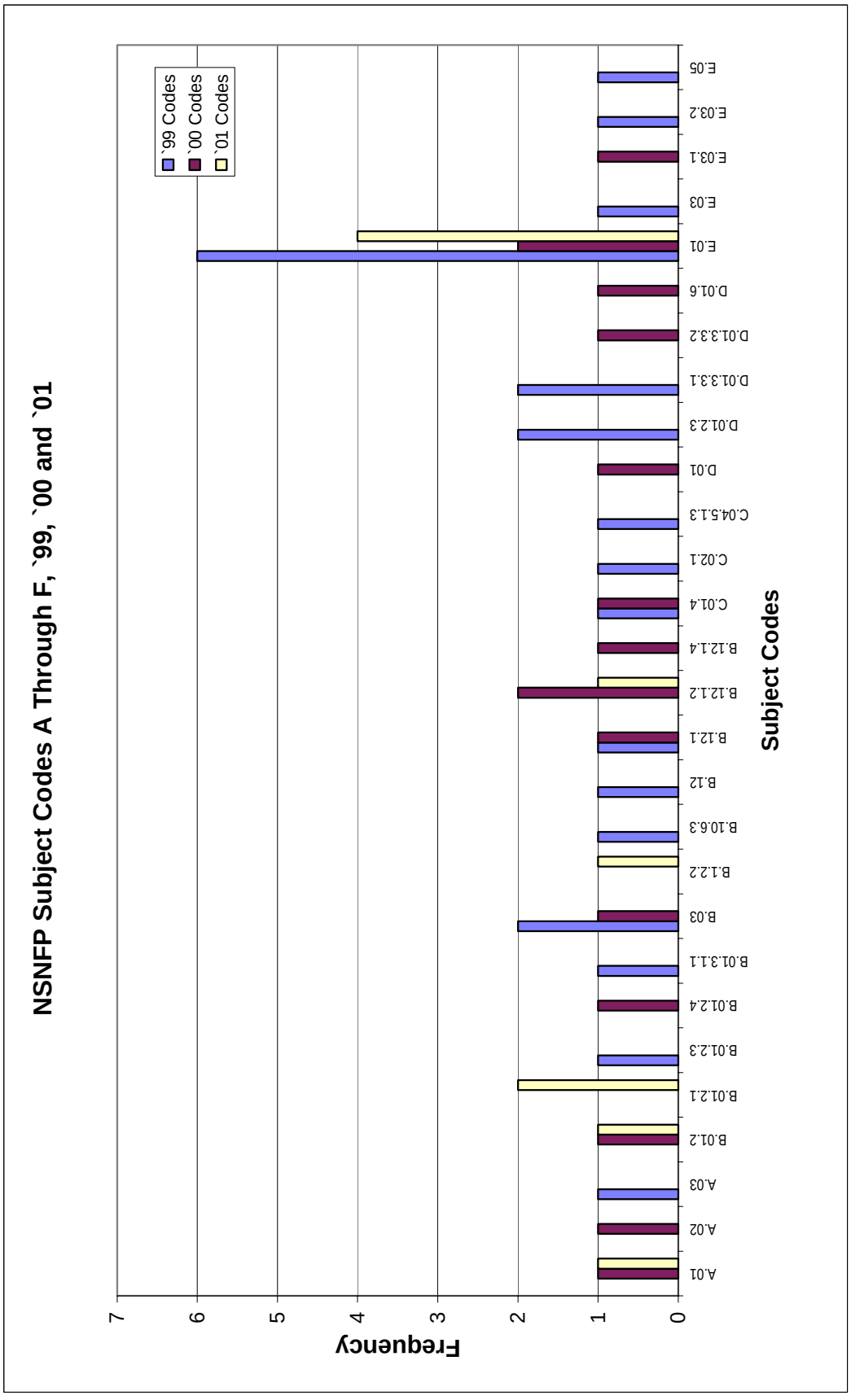
1. National Spent Nuclear Fuel Quality Assurance Program Annual Trending Report, January-December 2000

2. National Spent Nuclear Fuel Quality Program Annual Trending Report, January–December 1999, TS-QAD-00-041.

Attachment B

Figures

NSNFP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B.01.2.4
B.01.3.1.1
B.03
B.1.2.2
B.10.6.3
B.12
B.12.1
B.12.1.2
B.12.1.4
C.01.4
C.02.1
C.04.5.1.3
D.01
D.01.2.3
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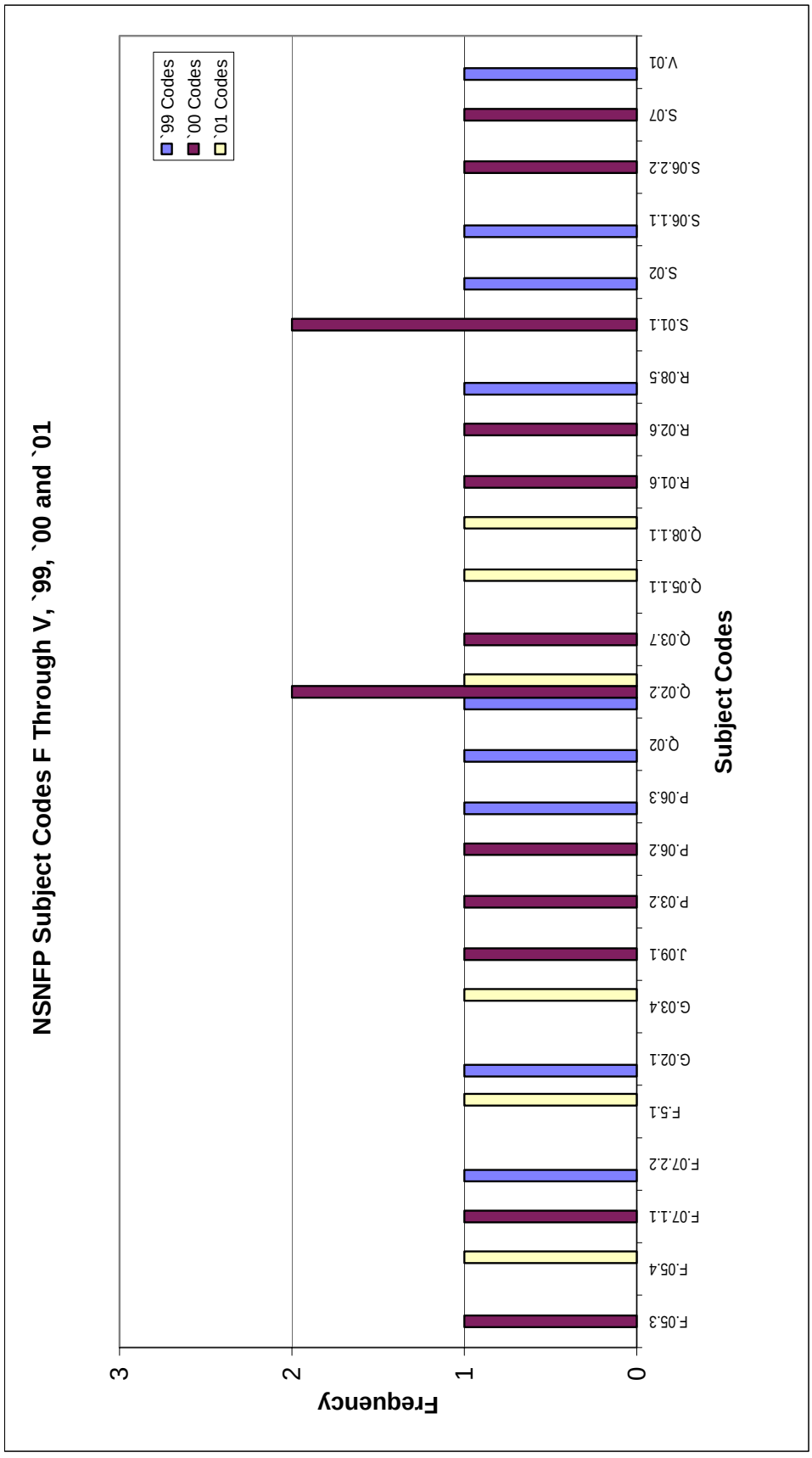
E.05

NSNFP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F.07.2.2
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G.03.4
J.09.1
P.03.2
P.06.2
P.06.3
Q.02
Q.02.2
Q.03.7
Q.05.1.1
Q.08.1.1
R.01.6
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S.06.2.2
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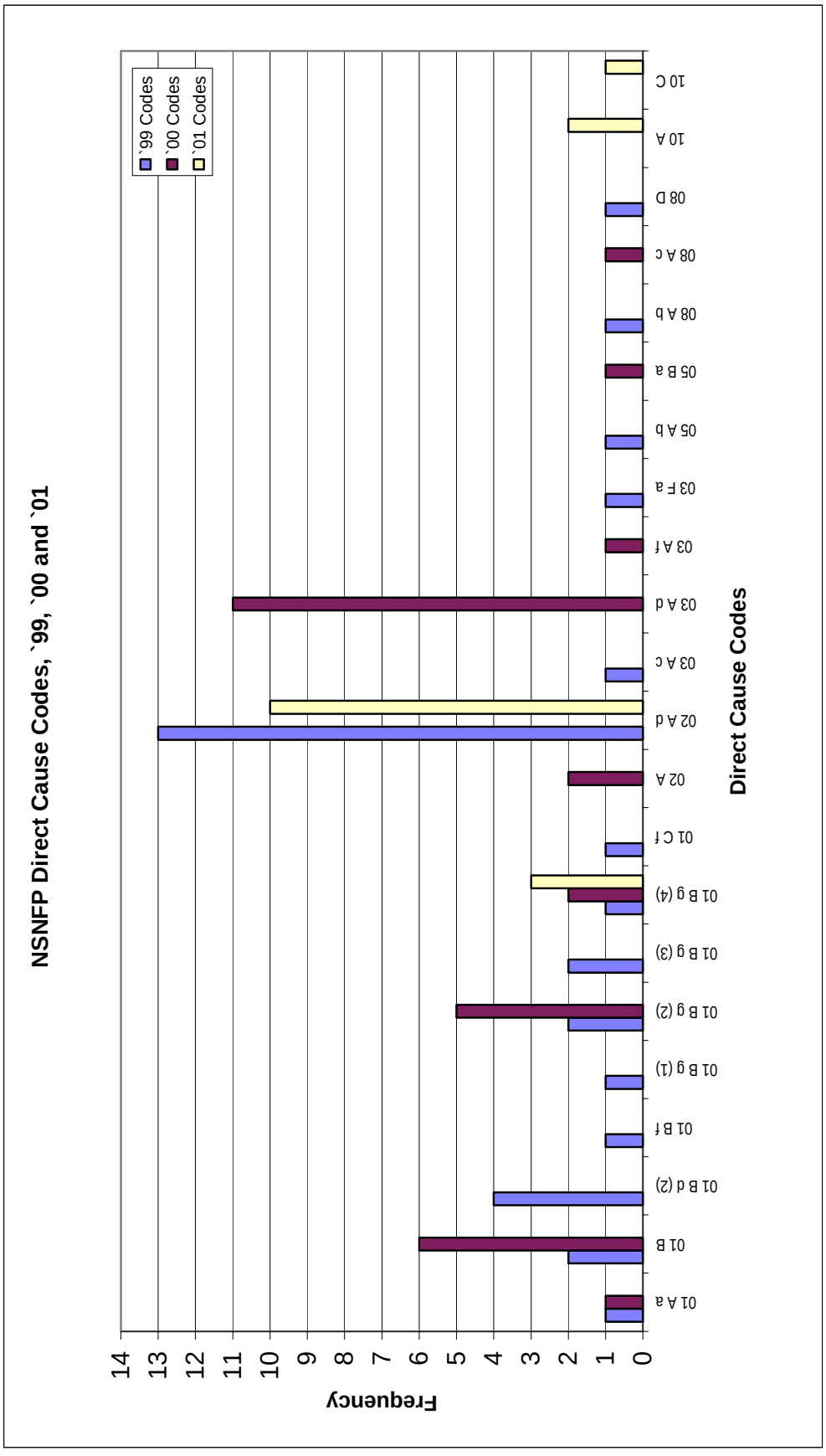
NSNFP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13
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01 B f
01 B g (1)
01 B g (2)
01 B g (3)
01 B g (4)
01 C f
02 A
02 A d
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03 A f
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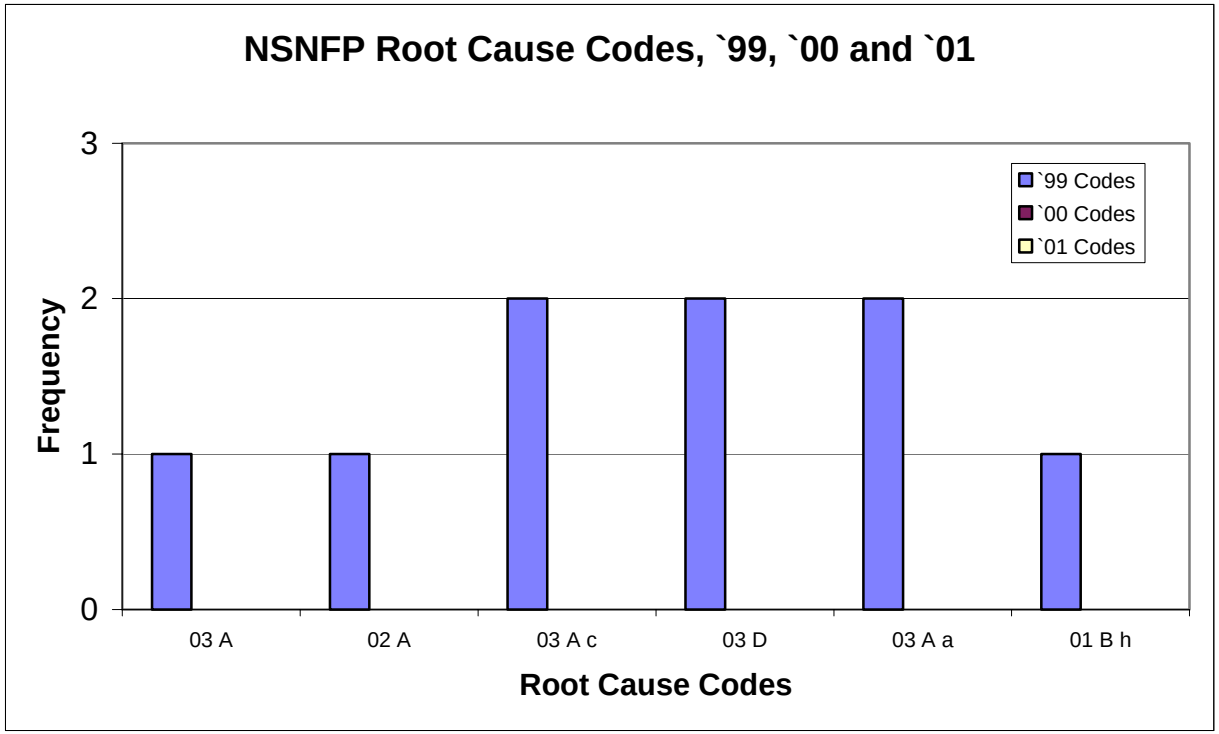
05 B a
08 A b
08 A c
08 D
10 A
10 C

NSNFP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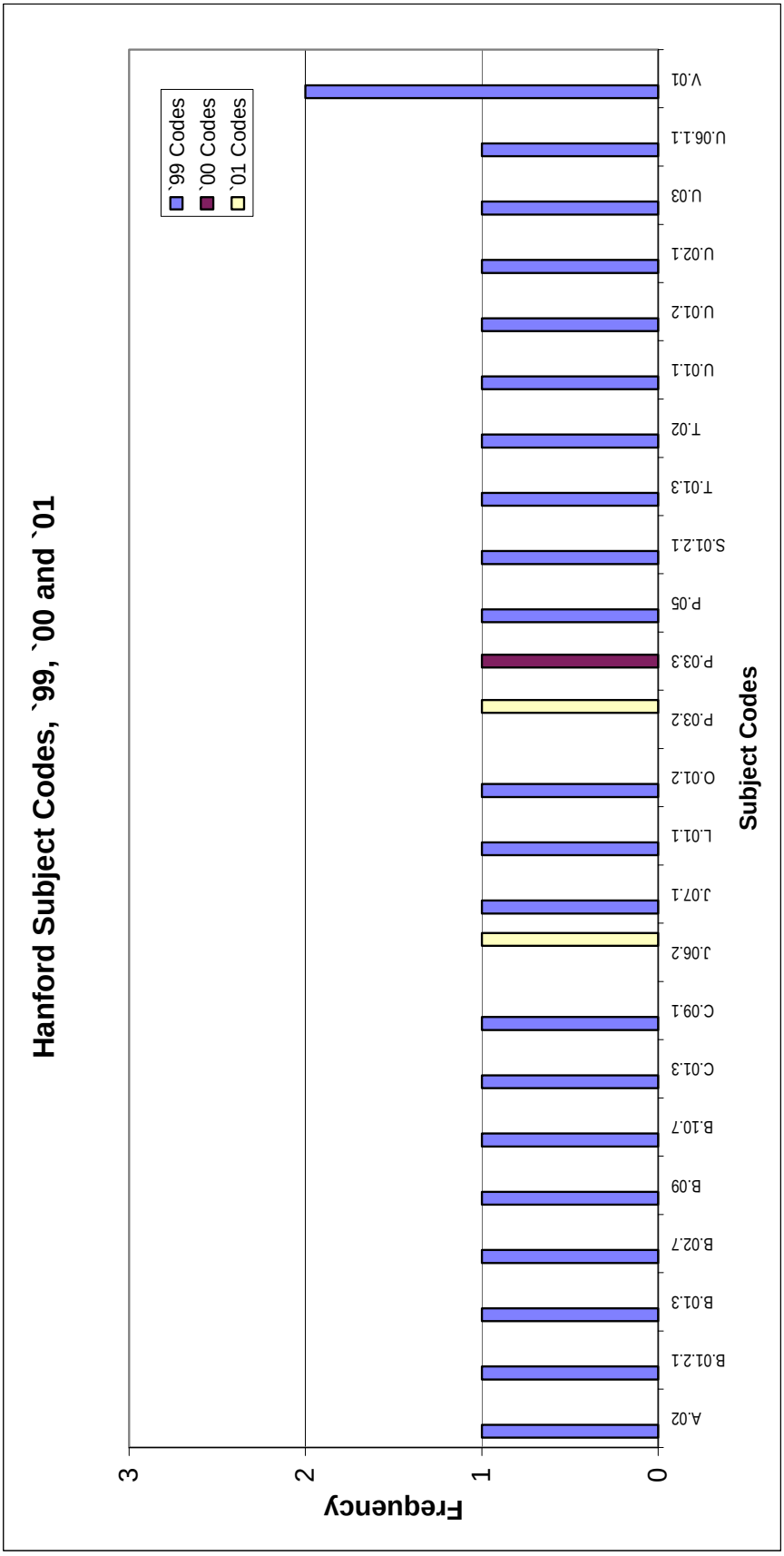
02 A
03 A c
03 D
03 A a
01 B h
Root Cause Codes

Hanford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B.01.3
B.02.7
B.09
B.10.7
C.01.3
C.09.1
J.06.2
J.07.1
L.01.1
O.01.2
P.03.2
P.03.3
P.05
S.01.2.1
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U.03
U.06.1.1
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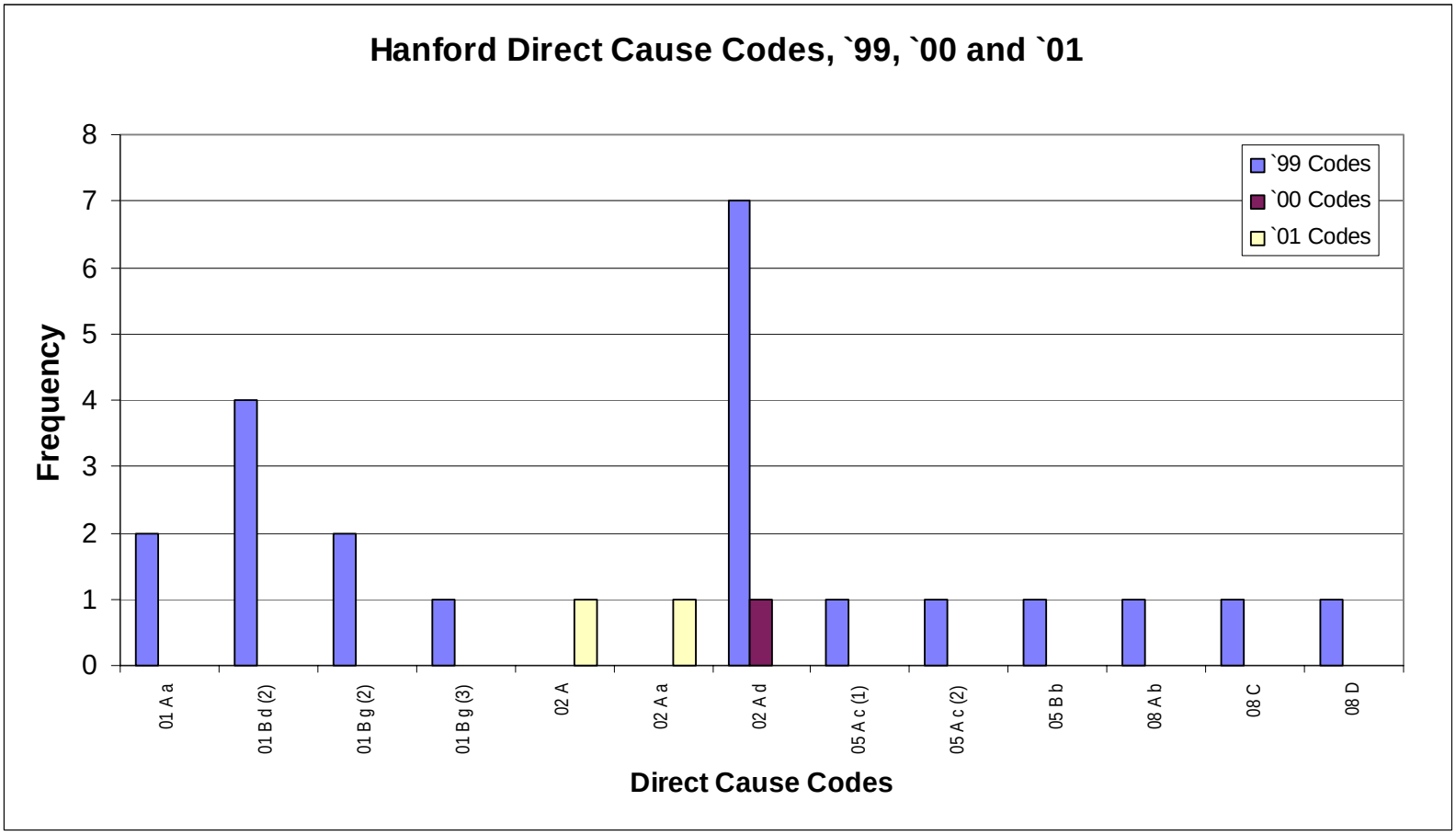
Hanford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`00 Codes
`01 Codes
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01 B d (2)
01 B g (2)
01 B g (3)
02 A
02 A a
02 A d
05 A c (1)
05 A c (2)
05 B b
08 A b
08 C
08 D
Direct Cause Codes

INEEL

Subject Codes

Subject Code	1998	1999	2001
A.02	1		
B.01	1		
B.01.2	3		
B.01.2.2	1		
B.01.3	1		
B.02	1		
B.05	2		
B.06	1		
B.07	1		
B.11	1		
B.12	1		
C	1		
E.01	1		
F	1		
G.06.3.4	1		
L.01.6	1		
M.01	1		
O.01	1		
P	1		
Q	1		
R.03	1		
R.06.3		1	
V.01	1		
B.12.1.4			1

INEEL

Direct Cause Codes

Direct Cause Code	1998	1999	2001
01 A a	2		
01 B d (2)	4		
01 B e	1		
01 B g (1)	1		
01 B g (2)	10		
01 B g (3)	3		
02 A d	2	1	
04 C a	1		
08 A b	1		
02 A			1

Root Cause Codes

Root Cause Code	1998	1999	2001
01 A a	1		
01 B c	1		
03 A b	1		
03 A c	6		
03 A d	1		
03 A f	2		
03 C	1		
08 C	1		

ORNL

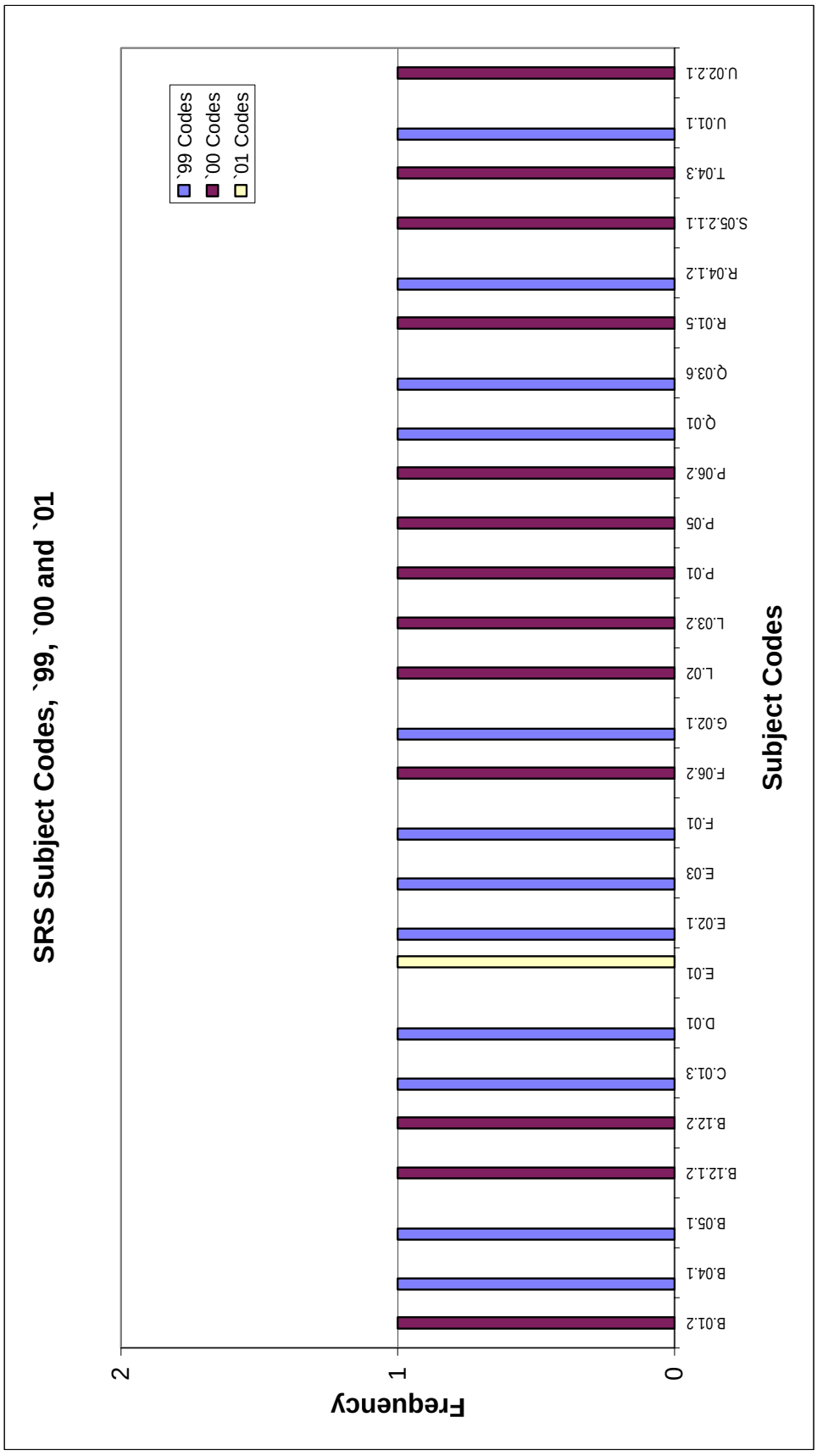
Subject codes

Subject Code	1998	2000
Q.01.1.7		1
R.01.5	1	
R.21.2.1		1

Direct Cause Codes

Direct Cause Code	1998	2000
01 B d (2)		1
02 A b		1
03 F a	1	

SRS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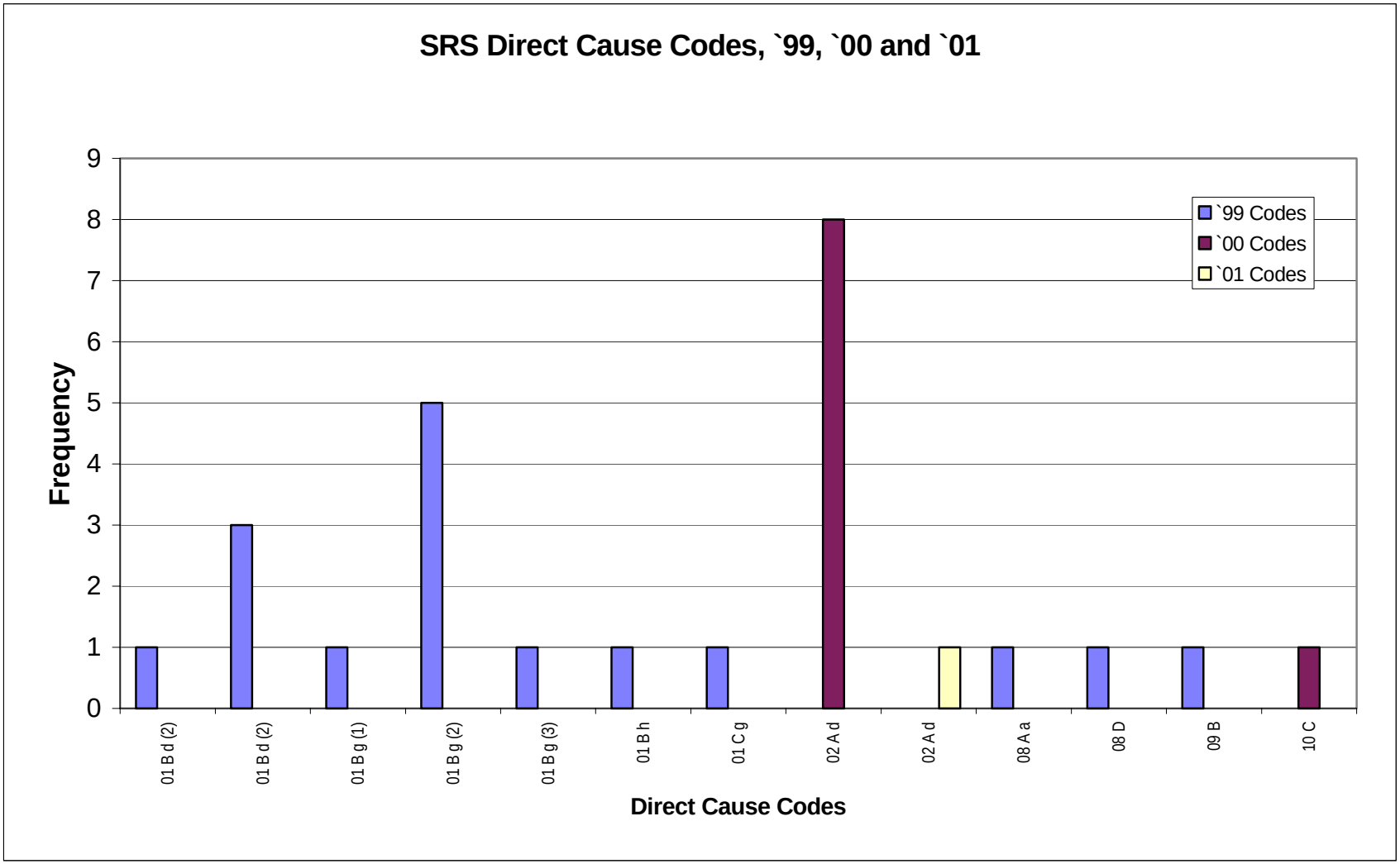
C.01.3
D.01
E.01
E.02.1
E.03
F.01
F.06.2
G.02.1
L.02
L.03.2
P.01
P.05
P.06.2
Q.01
Q.03.6
R.01.5
R.04.1.2
S.05.2.1.1
T.04.3
U.01.1
U.02.2.1

SRS


SRS Direct Cause Codes, `99, `00 and `01
Frequency
0
1
2
3
4
5
6
7
8
9
`99 Codes
`00 Codes
`01 Codes
01 B d (2)
01 B d (2)
01 B g (1)
01 B g (2)
01 B g (3)
01 B h
01 C g
02 A d
02 A d
08 A a
08 D
09 B
10 C
Direct Cause Codes

NSNFP Supplier

Argonne National Laboratory-East

Subject Codes

Subject Code	1999	2000	2001
A.02	1		
B.12.2.4	1		
G.11.3	1		
L.07.3	1		

Direct Cause Codes

Direct Cause Code	1999	2000	2001
01 A a	1		
02 A d	3		

NSNFP Supplier

Argonne National Laboratory-West

Subject Codes

Subject Code	1999	2000	2001
B.10.7		1	
E.01	1		
F.04	1		
F.05.4	1		
G.02.1	2		
Q.05	1		

Direct Cause Codes

Direct Cause Code	1999	2000	2001
01 B a	1		
01 B g (2)			
01 B g (2)	2		
02 A d	2		
02 A d			
05 B		1	
09 B	1		

NSNFP Supplier

Battelle-Pacific Northwest National Laboratory

Subject Codes

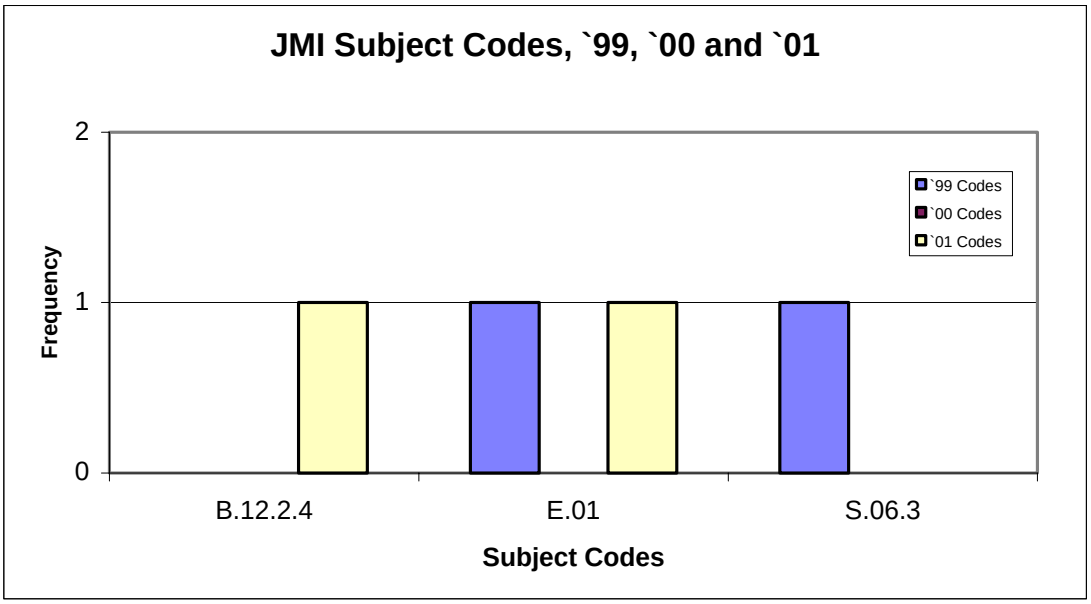
Subject Code	1999	2000	2001
L.01.1	1		
Q.05.1	1		
S.01.2	1		
U.02.2.2	1		

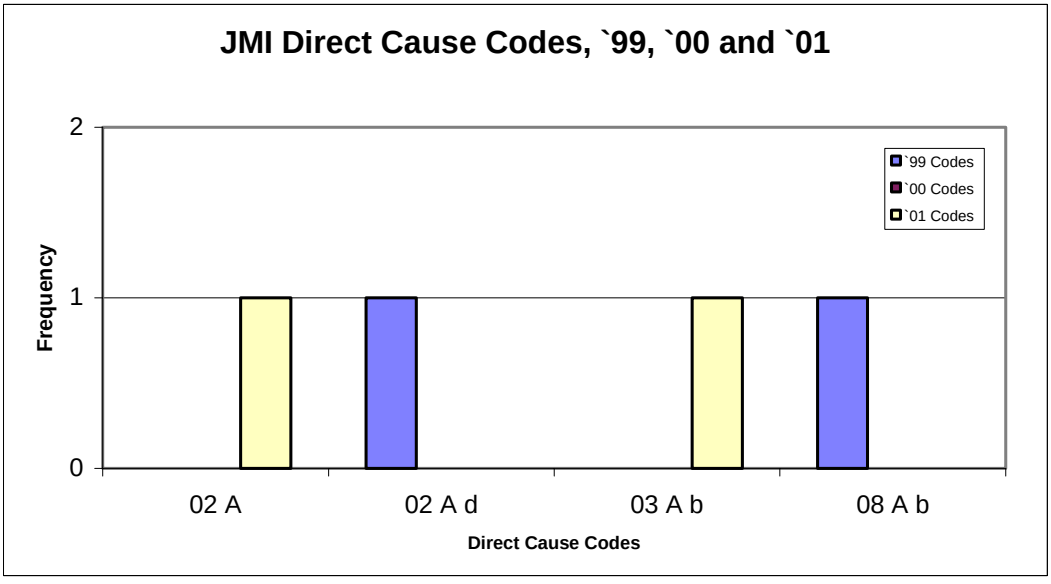
Direct Cause Codes

Direct Cause Code	1999	2000	2001
02 A d	3		
08 A b	1		

NSNFP Supplier

JMI Inc.





NSNFP Supplier

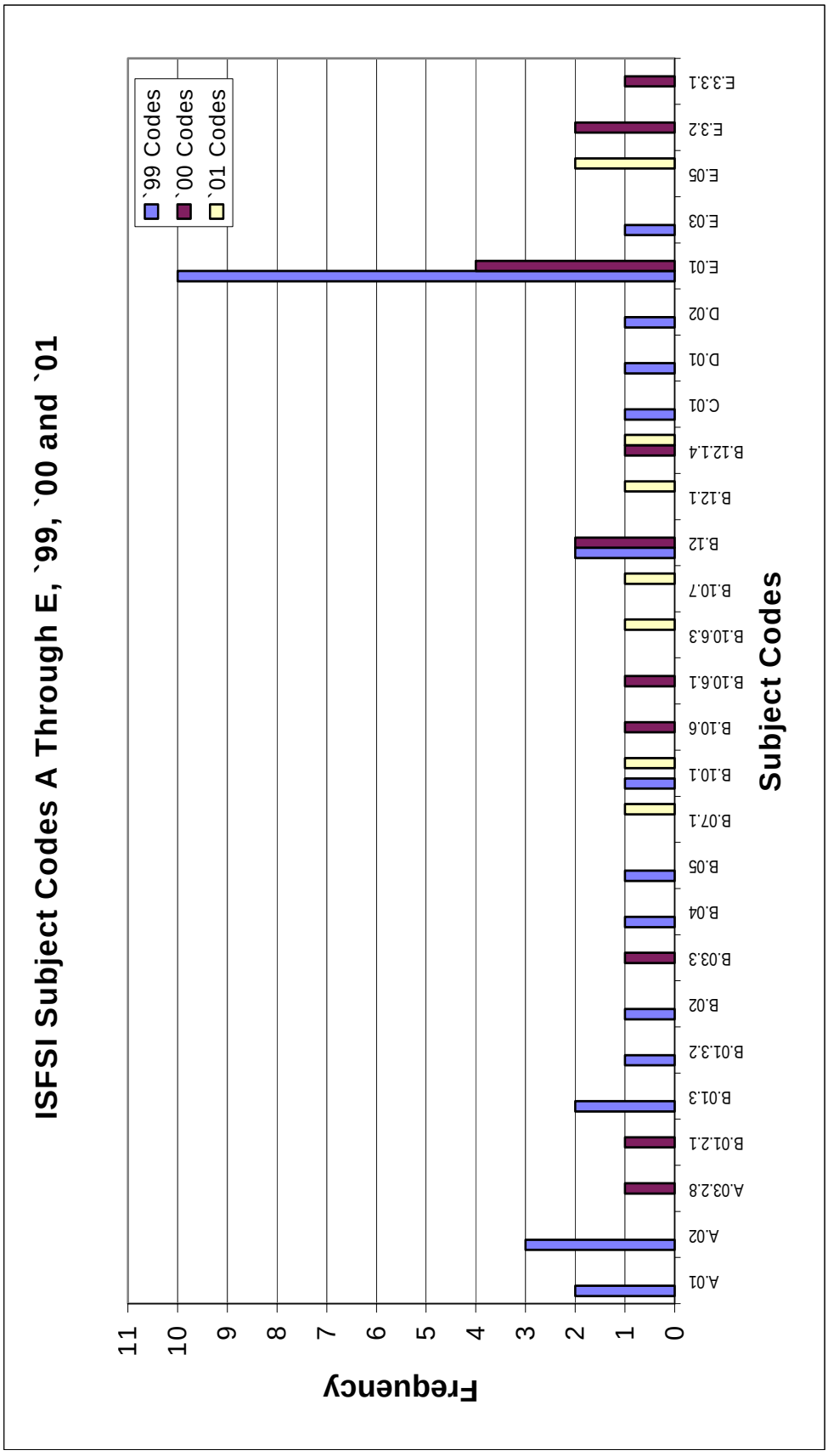
Lockheed Martin Energy Systems-Oak Ridge-Y12

Subject Codes

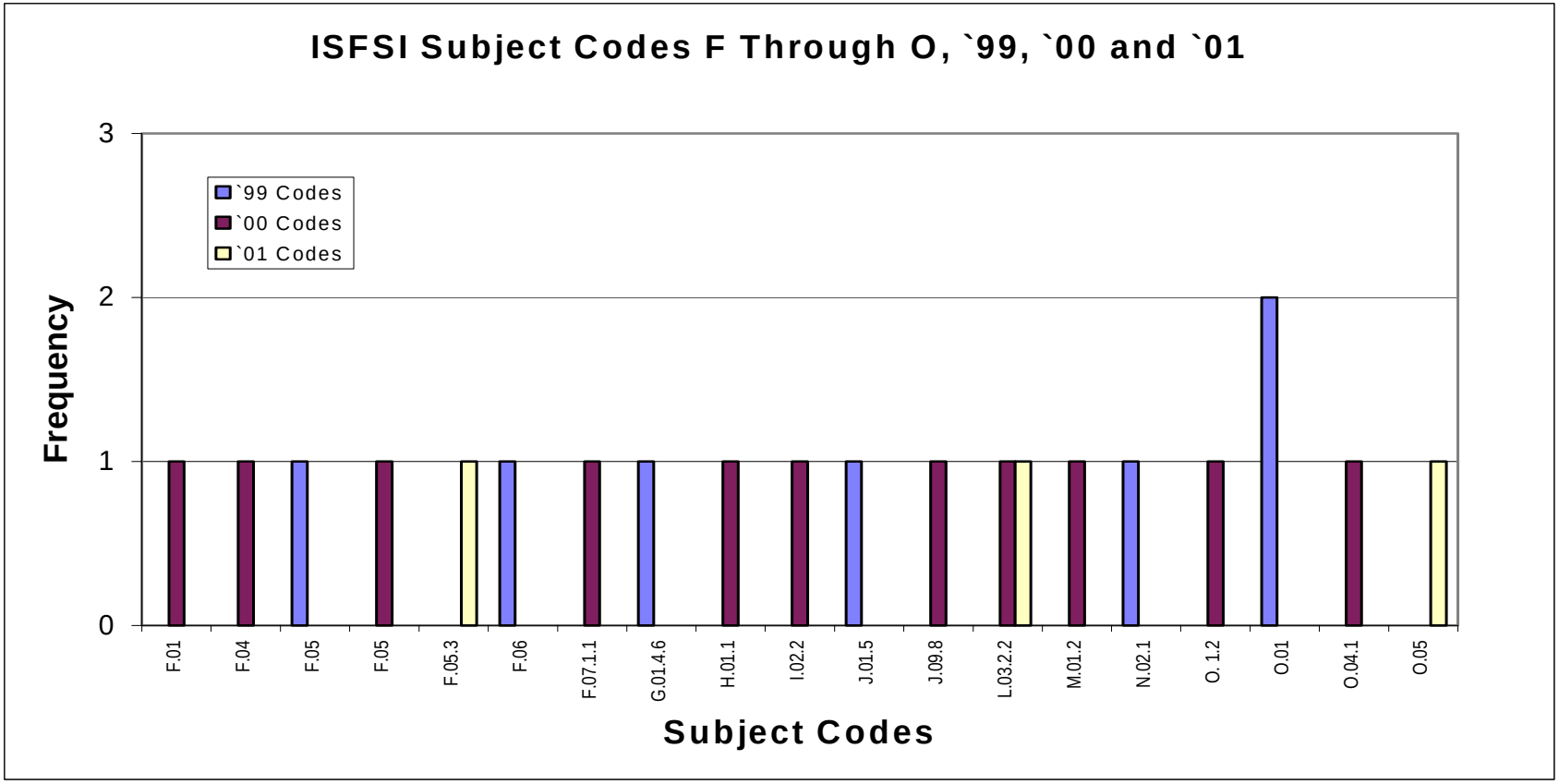
Subject Code	1998	2000	2001
B.05.6	1		
B.12.2.4	1		
E.01	1		
G.02.1	1		
L.01.5	1		
L.07	1		
Q.11.1	1		

Direct Cause Codes

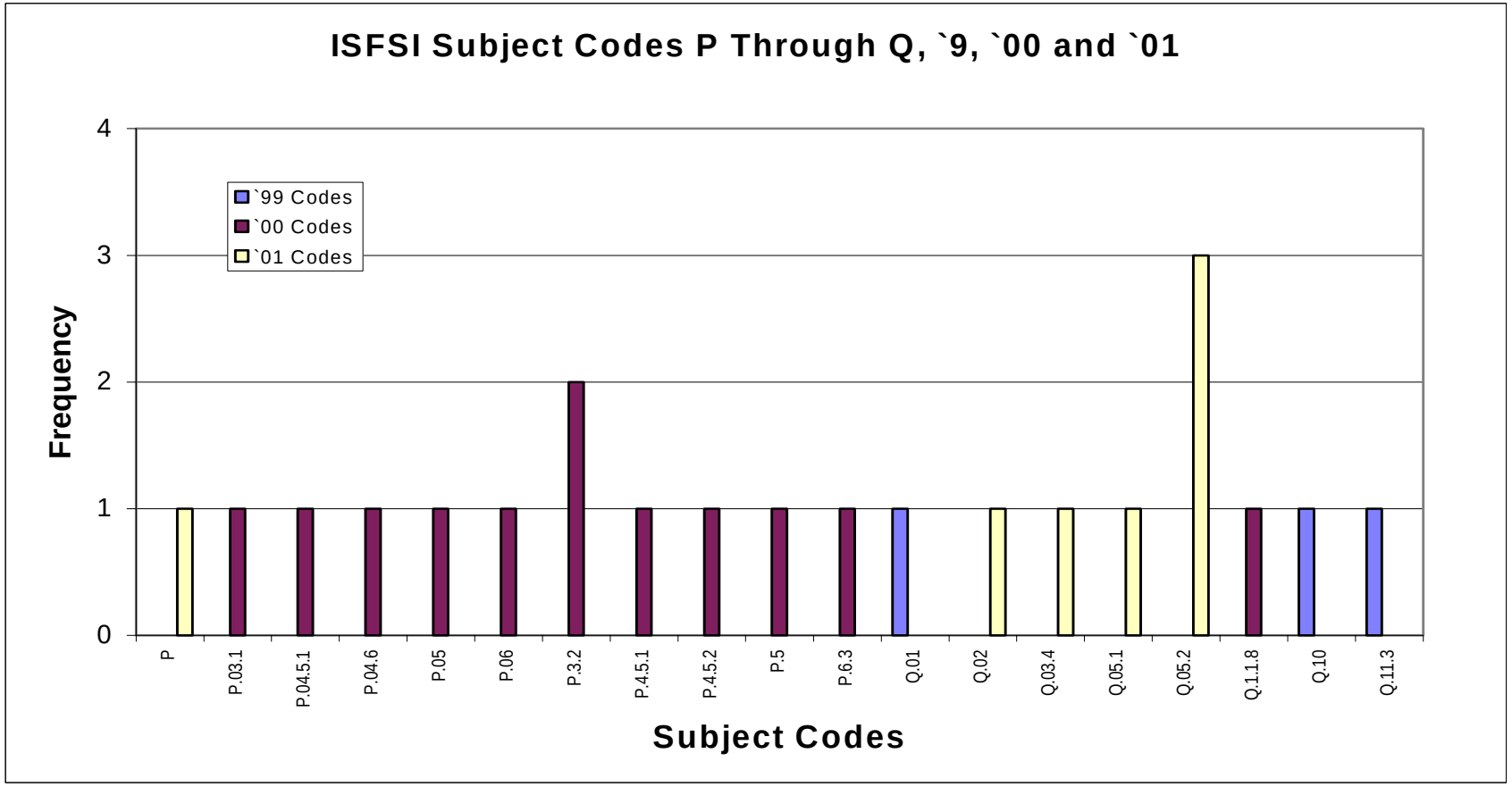
Direct Cause Code	1999	2000	2001
01	1		
01 A a	1		
01 A d	1		
01 B d (1)	1		
01 B g (4)	1		
02 A d	1		
09 B	1		


ISFSI Subject Codes A Through E, `99, `00 and `01
`99 Codes
`00 Codes
`01 Codes
Frequency
0
1
2
3
4
5
6
7
8
9
10
11
Subject Codes
A.01
A.02
A.03.2.8
B.01.2.1
B.01.3
B.01.3.2
B.02
B.03.3
B.04
B.05
B.07.1
B.10.1
B.10.6
B.10.6.1
B.10.6.3
B.10.7
B.12
B.12.1
B.12.1.4
C.01
D.01
D.02
E.01
E.03
E.05
E.3.2
E.3.3.1

Independent Spent Fuel Storage Installations



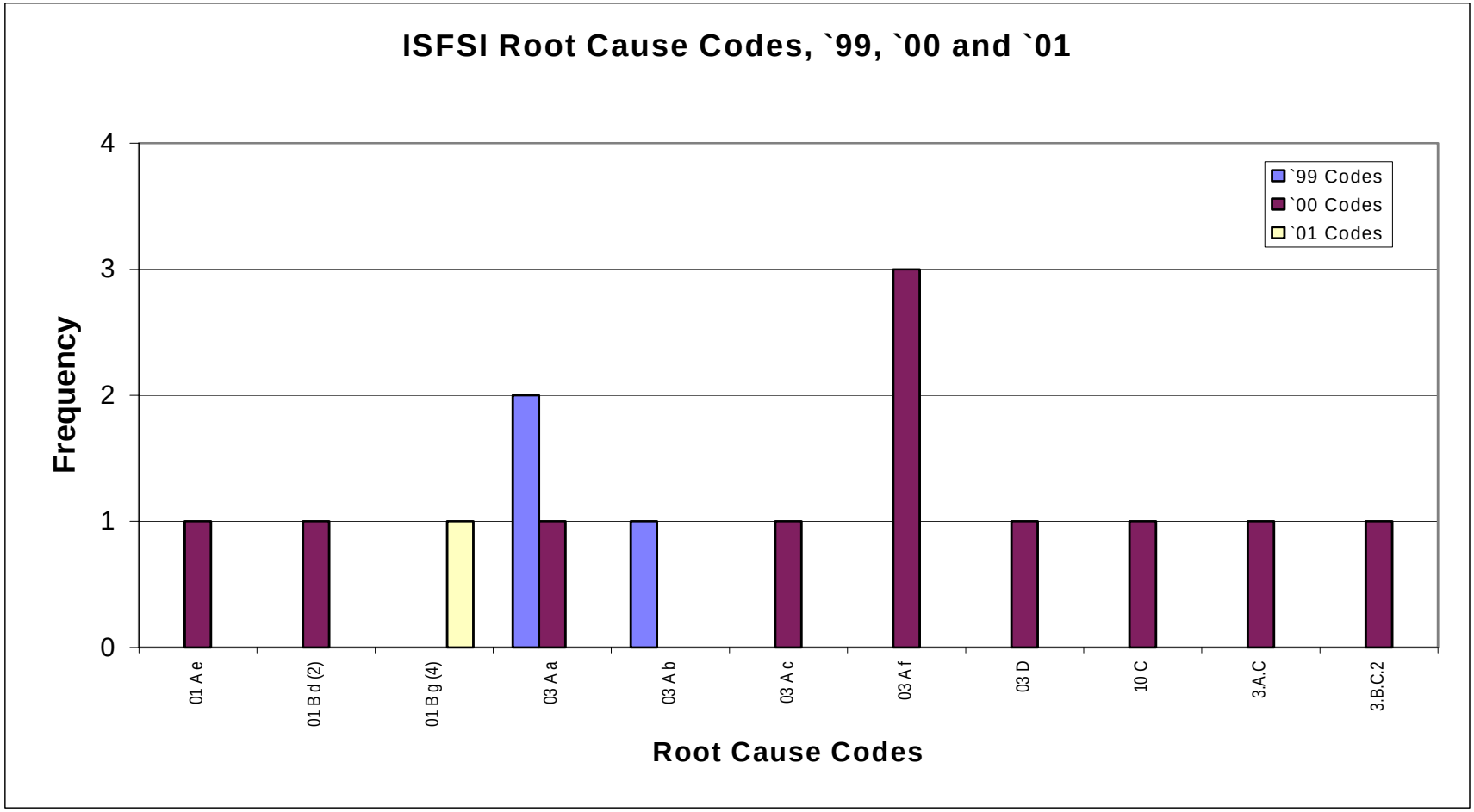
Independent Spent Fuel Storage Installations



Independent Spent Fuel Storage Installations

ISFSI Direct Cause Codes, `99, `00 and `01

Independent Spent Fuel Storage Installations



Corrective Action Duration Tables

NSNFP & NSNF QA

	NSNFP QA		NSNFP	
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA	1	812
Closed `99	15	260.5	17	329.4
Open `00	1	541	6	526.1
Closed `00	5	176.4	18	217.7
Open `01	3	106	8	216.8
Closed `01	2	48.5	3	21.3

SNF Sites

Hanford		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA
Closed `99	22	407
Open `00	0	NA
Closed `00	1	0
Open `01	0	NA
Closed `01	2	0

SNF Sites

INEEL		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `98	0	NA
Closed `98	25	765.7
Open `99	0	NA
Closed `99	1	182
Open `00	0	NA
Closed `00	0	NA
Open `01	1	245
Closed `01	0	NA

ORNL		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `98	0	NA
Closed `98	1	281
Open `00	0	NA
Closed `00	2	0

SNF Sites

SRS		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA
Closed `99	12	262.9
Open `00	2	419
Closed `00	11	235.4
Open `01	1	300
Closed `01	0	NA

National Spent Nuclear Fuel Program Suppliers

Organization-DR/CAR Status	Number of Deficiencies	Average Number of Days Open
ANL-E Closed	4	209.5
ANL-W Closed	7	190
Battelle-PNNL Closed	4	116.3
LMES-OR-Y12 Closed	7	85
JMI Closed	2	224
JMI Inc. Open	1	88

Independent Spent Fuel Storage Installations

DOE-ID ISFSIs		
Status of DR/CAR and Year Issued	Number of DRs/CARs	Average Number of Days Open
Open `99	0	NA
Closed `99	38	363.7
Open `00	0	NA
Closed `00	38	253
Open `01	10	74
Closed `01	8	91.3

ATTACHMENT C

SUBJECT CODES

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
Section 1	**ORGANIZATION**	**A**
1.2	1.2 REQUIREMENTS Each Affected Organization shall prepare one or more controlled documents, accepted by the OCRWM Office of Quality Assurance that describes internal and external organizational interfaces, organizational structures, requirements, and responsibilities for its scope of work.	A.1
1.2.1	1.2.1 Line Management Each Affected Organization shall identify the responsibilities and authorities of those organizations and management positions responsible for achieving and maintaining quality.	A.2
  1.2.2.:1s	1.2.2 Quality Assurance Management The Director, Office of Quality Assurance, is the management position responsible for performing the QA function for the OCRWM Program; authority to execute this responsibility may be delegated to the Affected Organization.	A.3 A.3.1
1.2.2H.	H. Have the authority to stop work when significant conditions adverse to quality warrant such action.	A.3.2.8
SECTION 2	**QUALITY ASSURANCE PROGRAM**	**B**
2.2 2.21 2.2.1A.	2.2 REQUIREMENTS 2.2.1 Quality Assurance Program Documents A. Affected Organizations shall issue a policy statement signed by senior line management directing mandatory compliance with this QA program.	 B.1 B.1.1
2.2.1B.:1s	B. Affected Organizations shall establish implementing documents applicable to their scope of work that translate QARD requirements into work processes.	B.1.2
  2.2.1B.1.	The following requirements apply to implementing documents. 1. Each Affected Organization shall establish a structured system of implementing documents that provides for top down implementation of the QARD or, if stipulated in procurement documents, shall work to the implementing documents of another Affected Organization.	 B.1.2.1
2.2.1B.2.	2. The system shall accommodate the size and location(s) of the organization, the organizational structure, and the nature of the work such that management processes will be carried out efficiently and effectively.	B.1.2.2
2.2.1B.3.	3. The system shall provide positive control over external interfaces between Affected Organizations and internal interfaces within an organization.	B.1.2.3

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
2.2.1B.4.	4. Each Affected Organization shall review revisions to the QARD and incorporate changes into their implementing documents, as appropriate.	B.1.2.4
2.2.1C.	C. Each Affected Organization shall complete a QARD requirements matrix for the portion of the QARD which they are implementing.	B.1.3
2.2.1C.1.a.	1. The matrix shall identify: a. Where the QARD requirements are directly addressed.	B.1.3.1 B.1.3.1.1
2.2.1C.2.	2. Initial QARD requirements matrices shall be reviewed by OQA in accordance with QARD Subsection 2.2.10, Document Review.	B.1.3.2
2.2.2	2.2.2 Classifying Items The QA program shall apply to the following, which shall be included on a Q-List.	B.2
2.2.2.D.	D. Items required for the protection of items important to safety and waste isolation from the hazards of fire.	B.2.4
2.2.2.G.	G. Items required to control occupational radiological exposure.	B.2.7
2.2.3C.	C. The QA program shall apply to those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.	B.3.3
2.2.4A.	2.2.4 Applying Quality Assurance Controls QA controls (grading) shall be applied to the degree commensurate with the: A. Function or end use of the item.	B.4 B.4.1
2.2.5 2.2.5.:1s	2.2.5 Planning Work Planning shall be documented to ensure work is accomplished under suitably controlled conditions.	B.5
2.2.5A.	Planning elements shall include, as appropriate: A. Definition of the work scope, objectives, and a listing of the primary tasks involved.	B.5.1
2.2.5F.	F. Identification of, or provisions for the identification of required records, and the recording of objective evidence of the results of the work performed.	B.5.6

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
2.2.6 2.2.6.:1s	2.2.6 Surveillances Surveillances shall be conducted to evaluate the quality of selected work subject to the QARD.	B.6
2.2.7.:1s	2.2.7 Management Assessments The Office of Civilian Radioactive Waste management shall perform or direct the performance of management assessments of Affected Organizations by personnel outside the QA organization.	B.7
2.2.9 2.2.9A.	2.2.8 Peer Reviews A. Peer reviews shall be conducted when the adequacy of information or the suitability of implementing documents and methods essential to meet specified objectives cannot be established through testing, alternate calculations, or reference to previously established standards and practices.	B.9 B.9.1
2.2.10B.	B. Pertinent background information or data shall be made available to the reviewers by the organization requesting the review if the information is not readily available to the reviewer.	B.10.3
2.2.10E.	E. The scope of the review shall consider all aspects of the document.	B.10.6
2.2.10E.1.:1s	1. Each organization or technical discipline affected by the document shall review the document according to the established review criteria.	B.10.6.1
2.2.10E.2.:1s	2. The QA organization shall review implementing documents and changes thereto that translate the QARD into work processes as described in Subsection 2.2.1, Quality Assurance Program Documents.	B.10.6.3
2.2.10F.	F. Mandatory comments resulting from the review shall be documented and resolved before approving the document.	B.10.7
  2.2.11.:1s	2.2.10 Quality Assurance Program Information Management Affected Organization management shall on a continuing basis be appraised of the status, adequacy and compliance aspects of the QA Program.	B.11 B.11.1
2.2.11.:2s	Appropriate management shall receive, as a minimum, audit reports, surveillance reports, trend reports, and management assessment reports.	B.11.2
2.2.12 2.2.12A.	2.2.11 Personnel Qualification A. Each Affected Organization shall indoctrinate and train personnel as follows.	B.12 B.12.1
2.2.12A.2.	2. Ensure personnel are indoctrinated and trained, as needed, to achieve initial proficiency; maintain proficiency; and to adapt to changes in technology, methods, or job responsibilitities.	B.12.1.2

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
2.2.12A.4.	4. Ensure indoctrination and training are completed prior to performing the work.	B.12.1.4
2.2.12B.	B. For personnel who perform or manage design, scientific investigation, software development activities and for personnel who verify or manage the verification of design, scientific investigation, software development activities, or items, Affected organizations shall ensure that:	B.12.2
2.2.12B.4.	4. Minimum education and experience are verified or, when minimum education and experience cannot be verified, documented justification is provided for the personnel assignment.	B.12.2.4
SECTION 3	**DESIGN CONTROL** 3.1 This section provides requirements to ensure that designs are defined, controlled, and verified.	**C**
3.2 3.2.1	3.2 REQUIREMENTS 3.2.1 Design Input Control Applicable design inputs (such as design bases, conceptual design reports, performance requirements, regulatory requirements, codes, and standards) shall be controlled by those responsible for the design according to the following requirements:	 C.1
3.2.1C	C. Changes from approved design inputs and reasons for the changes shall be identified, approved, documented, and controlled.	C.1.3
3.2.1D	D. Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds.	C.1.4
3.2.2 3.2.2A.	3.2.2 Design Process The design process shall be controlled according to the following requirements: A. Design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner.	C.2 C.2.1
3.2.4E.1.:3s	Unverified portions of the design shall be clearly identified and controlled.	C.4.5.1.3
3.2.9 3.2.9A.	3.2.9 Design Interface Control A. Design interfaces shall be identified and controlled.	C.9 C.9.1

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
SECTION 4	**PROCUREMENT DOCUMENT CONTROL**	**D**
4.2 4.2.1	4.2 REQUIREMENTS 4.2.1 Procurement Document Preparation Procurement documents issued by each Affected Organization shall include the following provisions, as applicable, to the items or service being procured:	 D.1
4.2.1B.3.	3. Tests, inspections, or acceptance requirements that the purchaser will use to monitor and evaluate the performance of the supplier shall be specified.	D.1.2.3
4.2.1C.3.:1s	3. When deemed appropriate, the purchaser shall permit some or all supplier work to be performed under the purchaser's or another Affected Organization's QA program provided the work is adequately addressed.	D.1.3.3.1
4.2.1C.3.:2s	In these cases, procurement documents shall specify that the purchaser's or another Affected Organization's implementing documents are applicable to the supplier and that the purchaser shall provide these applicable documents to them.	D.1.3.3.2
4.2.1F.	F. Documentation required to be submitted to the purchaser for information, review, or acceptance:	D.1.6
4.2.2 4.2.2A.	4.2.2 Procurement Document Review and Approval A. Procurement document reviews in accordance with Subsection 2.2.10, Document Review, shall be performed and documented prior to issuance of the procurement documents to the supplier.	D.2 D.2.1
4.2.2B.	B. A review of the procurement documents and any changes thereto shall be made to verify that documents include appropriate provisions to ensure that items or services will meet the governing requirements.	D.2.2
4.2.2C.	C. Reviews shall ensure that all applicable technical and QA program requirements are included.	D.2.3
4.2.2D.	D. Reviews shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and scope of the procurement.	D.2.4
4.2.2E.	E. Procurement document reviewers shall include representatives from the technical and QA organizations.	D.2.5
4.2.2F.	F. Procurement documents shall be approved.	D.2.6
SECTION 5	**IMPLEMENTING DOCUMENT**	**E**
5.2	Section 5.2 REQUIREMENTS Work shall be performed in accordance with controlled implementing documents.	E.1

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
  5.2.1:1s	5.2.1 Types of Implementing Documents The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed.	E.2 E.2.1
5.2.2	5.2.2 Content of Implementing Documents Implementing documents shall include the following information as appropriate to the work to be performed:	E.3
5.2.2A.	A. Responsibilities and organizational interfaces of the organizations affected by the document.	E.3.1
5.2.2B.	B. Technical and regulatory requirements.	E.3.2
5.2.2C.:1s	C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations.	E.3.3.1
5.2.4	5.2.4 Compliance with Implementing Documents Individuals shall comply with implementing documents, however:	E.5
SECTION 6	**DOCUMENT CONTROL** This section establishes requirements to ensure documents, including changes thereto, are reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed.	**F**
6.2 6.2.1	6.2 REQUIREMENTS 6.2.1 Types of Documents Implementing documents and documents that specify technical requirements or quality requirements shall be controlled in accordance with this Sec.	 F.1
6.2.4	6.2.4 Approving Documents The organizational position responsible for approving the document for release shall be identified.	F.4
6.2.5	6.2.5 Distribution and Use of Documents The distribution and use of documents, including changes and editorial corrections to documents, shall include the following:	F.5
6.2.5A.	A. Documents, either in hard copy or electronic media, used to perform work shall be distributed to, or made available to, and used at, the work location.	F.5.1
6.2.5C.	C. The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.	F.5.3

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
6.2.5D.	D. A method shall be established to identify the current status of each document that is required to be controlled in accordance with this Sec.	F.5.4
6.2.6A.	6.2.6 Changes to Documents A. Changes to documents shall be reviewed in accordance with the requirements of Subsection 2.2.10, Document Review, prior to approval for release.	F.6 F.6.1
6.2.6B.	B. Changes shall be approved for release by the designated organizational position that is responsible for the document.	F.6.2
6.2.7A.:1s	A. After the expedited change has been authorized, the changes shall be processed through normal change process.	F.7.1.1
6.2.7B.2.	2. The time limits for processing expedited changes through the normal change process shall be specified.	F.7.2.2
SECTION 7	**CONTROL OF PURCHASED ITEMS AND SERVICES**	**G**
7.2 7.2.1	7.2 REQUIREMENTS 7.2.1 Procurement Planning Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:	 G.1
7.2.2 7.2.2A.	7.2.2 Source Evaluation and Selection A. Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.	G.2 G.2.1
7.2.3D.	D. Supplier QA programs shall be evaluated either before or after contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to the QARD.	G.3.4
7.2.6C.4.	4. Surveillance or audit of the work.	G.6.3.4
SECTION 8	**IDENTIFICATION AND CONTROL OF ITEMS**	**H**
SECTION 9	**CONTROL OF SPECIAL PROCESSES**	**I**
9.2.2	9.2.2 Personnel, Implementing Documents, and Equipment Qualifications Implementing documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Special process implementing documents shall include or reference	I.2
SECTION 10	**INSPECTION**	**J**
10.2.1.E	E. Identification of the functional qualification level (category or class) of personnel performing inspections.	J.1.5

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
10.2.6.B	B. Documentation not previously examined shall be examined for adequacy and completeness.	J.6.2
10.2.7 10.2.7.A	10.2.7 Accepting Items A. The acceptance of an item shall be documented and approved by qualified and authorized personnel.	J.7 J.7.1
10.2.9 10.2.9.A	10.2.9 Qualifications of Inspection and Test Personnel A. Qualifications Personnel performing inspections as described in this section and personnel performing tests as described in Section 11.0 shall be qualified according to the indoctrination and training, education and experience, and physical requirements of this Section. These personnel shall have experience or training commensurate with the scope, complexity, or special nature of the inspections or tests.	J.9 J.9.1
10.2.9.H	H. Periodic Evaluation of Qualification for Inspection and Test Personnel	J.9.8
SECTION 11	**TEST CONTROL**	**K**
Section 12	**CONTROL OF MEASURING AND TEST EQUIPMENT**	**L**
12.0 12.1 12.2.1.A	Requirements 12.2.1 Calibration A. Measuring and test equipment including equipment that contains software or programmable hardware, shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards. Software developed or modified by the user shall be controlled in accordance with Supplement I, Software. If no nationally recognized standards or physical constants exist, the basis for calibration shall be documented.	L.1 L.1.1
12.2.1.E	E. Calibrated measuring and test equipment shall be labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration.	L.1.5
12.2.1.F	F. Calibrated measuring and test equipment shall be uniquely identified to provide traceability to its calibration data.	L.1.6
12.2.2	12.2.2 Documenting the Use of Measuring and Test Equipment The use of measuring and test equipment shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.	L.2
12.2.3.B	B. Out-of-Calibration measuring and test equipment shall be controlled. The controls shall include the following requirements:	L.3.2

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
12.2.3.B.2	2. When measuring and test equipment is found out-of-calibration during recalibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated.	L.3.2.2
12.2.7 12.2.7.A	12.2.7 Measuring and Test Equipment Documentation Measuring and test equipment calibration documentation shall include the following information: A. Identification of the measuring or test equipment calibrated.	L.7 L.7.1
12.2.7.B	B. Traceability to the calibration standard used for calibration.	L.7.2
12.2.7.C	C. Calibration data.	L.7.3
SECTION 13	**HANDLING, STORAGE, AND SHIPPING**	**M**
13.0 13.2.1 13.2.1.A	13.2 REQUIREMENTS 13.2.1 Controls A. Handling, storage, cleaning, packaging, shipping, and preservation of items shall be conducted in accordance with established work and inspection implementing documents, shipping instructions, or other specified documents.	 M.1 M.1.1
13.2.1.B	B. If required for critical, sensitive, perishable, or high-value articles, specific implementing documents for handling, storage, cleaning, packaging, shipping, and preservation shall be prepared and used.	M.1.2
SECTION 14	**INSPECTION TEST AND OPERATING STATUS**	**N**
14.2.2 14.2.2.A	14.2.2 Indicating Status A. The status of required inspection and tests of items shall be indicated when necessary to preclude inadvertent by-passing of such inspections and tests.	N.2 N.2.1
Section 15	**NONCONFORMANCES**	**O**
15.0 15.2.1 15.2.1.A	Requirements 15.2.1 Documenting and Evaluating Nonconforming Items A. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.	 O.1 O.1.1
15.2.1.B	B. Nonconformance documentation shall be reviewed, and recommended dispositions of nonconforming items shall be proposed. The review shall include determining the need for corrective action according to the requirements of Section 16.0, Corrective Action. In addition, organizations affected by the nonconformance shall be notified.	O. 1.2

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
15.2.4 15.2.4.A	15.2.4 Disposition of Nonconforming Items A. The disposition of "use-as-is," "reject," "repair," or "rework" for nonconforming items shall be identified and documented.	O.4 O.4.1
15.2.5	15.2.5 Quality Trending Nonconformance documentation shall be periodically analyzed by the Quality Assurance organization to identify quality trends in accordance with Section 16.0, Corrective Action.	O.5
SECTION 16.0,	**CORRECTIVE ACTION** This section establishes requirements to ensure conditions adverse to quality are promptly identifed and corrected as soon as practical.	P
16.2 16.2.1	16.2 REQUIREMENTS 16.2.1 Identifying Conditions Adverse to Quality A condition adverse to quality shall be identified when the Quality Assurance Requirements Document (QARD) or an implementing document requirement is not met.	 P.1
16.2.3 16.2.3A.	16.2.3 Conditions Adverse to Quality A. Conditions adverse to quality shall be documented and reported to the appropriate levels of management responsible for the conditions and to the quality assurance (QA) organization for tracking.	P.3 P.3.1
16.2.3B.	B. Responsible management shall determine the extent of the adverse condition and complete remedial action as soon as practical.	P.3.2
16.2.3C.	C. The QA organization shall concur with the proposed remedial action to ensure that QA program requirements are satisfied.	P.3.3
16.2.4E.:s1	E. Responsible management shall determine, document, and complete remedial action.	P.4.5.1
16.2.4E.:s2	Responsible management shall also determine the root cause of the problem and take corrective action to prevent recurrence as soon as practical.	P.4.5.2
16.2.4F.	F. The QA organization shall concur with the proposed corrective action including remedial action, the root cause, and actions taken to prevent recurrence to ensure that QA program requirements are satisfied.	P.4.6
16.2.5	16.2.5 Follow-up and Closure Action The QA organization shall verify implementation of corrective actions taken for all reported conditions adverse to quality and close the related corrective action documentation in a timely manner when actions are complete.	P.5

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16.2.6 16.2.6A.	16.2.6 Quality Trending A. The QA organization shall establish criteria for determining adverse quality trends.	P.6 P.6.1
16.2.6B.	B. Reports of nonconformance and conditions adverse to quality shall be evaluated to identify adverse quality trends and help identify root causes.	P.6.2
16.2.6C.	C. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends.	P.6.3
SECTION 17	**QUALITY ASSURANCE RECORDS** This section establishes requirements to ensure that Quality Assurance records are specified, prepared and maintained.	Q
17.2 17.2.1	17.2 REQUIREMENTS 17.2.1 Classifying Quality Assurance Records QA records shall be classified as lifetime or nonpermanent.	 Q.1
17.2.1A.7.	7. Personnel training and qualification documents for individuals executing QA program requirements.	Q.1.1.7
17.2.2 17.2.2A. 17.2.2A.1.	17.2.2 Creating Valid Quality Assurance Records A. Implementing documents shall: 1. Identify those documents that will become QA records.	Q.2 Q.2.1 Q.2.1.1
17.2.2A.2.	2. Identify the organization responsible for submitting the QA records to the records management system.	Q.2.1.2
17.2.2B.	B. Individuals creating QA records shall ensure that the QA records are legible, accurate, complete appropriate to the work accomplished, and identifiable to the items(s) or activity(s) to which they apply.	Q.2.2
17.2.3D.	D. Legibility and completeness of QA records shall be verified.	Q.3.4
17.2.3F.	F. QA records shall be indexed to ensure retrievability.	Q.3.6
17.2.3G.	G. QA records shall be submitted to storage after processing has been completed.	Q.3.7

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
17.2.5	17.2.5 Storing and Preserving Quality Assurance Records	Q.5
17.2.5A.	A. QA records shall be stored and preserved in predetermined storage facilities in accordance with an approved implementing document that provides:	Q.5.1
17.2.5A.1.	1. A description of the storage facility.	Q.5.1.1
17.2.5A.2.	2. A description of the filing system to be used.	Q.5.1.2
17.2.5A.3.	3. A method for verifying that the QA records received are in agreement with the transmittal document.	Q.5.1.3
17.2.5A.4.	4. A description of controls governing QA record access, retrieval, and removal.	Q.5.1.4
17.2.5A.5.	5. A method for filing supplemental information.	Q.5.1.5
17.2.5A.6.	6. A method for disposition of superseded QA records.	Q.5.1.6
17.2.5B	B. Storage methods shall be developed to preclude deterioration of QA records in accordance with the following:	Q.5.2
17.2.5B.1.	1. The storage area shall minimize the risk of damage or destruction by natural disasters, extremes in environmental conditions and infestations of pests or molds.	Q.5.2.1
17.2.8.	17.2.8 Turnover of Quality Assurance Records	Q.8
17.2.8A.:1s	A. Affected Organizations shall submit, to Office of Civilian Radioactive Waste Management (OCRWM) or the purchaser, those QA records being temporarily stored by them that are subject to records turnover requirements.	Q.8.1.1
17.2.11C.	C. The maximum time limit for keeping QA records in temporary storage shall be specified by OCRWM or the purchaser consistent with the nature or scope of work.	Q.11.3
Section 18	**AUDITS**	**R**
18.2.1E.	E. Internal audits of work to verify QA program compliance shall be performed annually or at least once during the life of the work, whichever is shorter.	R.1.5
18.2.1F.	F. Internal audits to determine QA program effectiveness (performance based audits) shall be performed on selected work.	R.1.6
18.2.2F.:1s	F. Annual performance evaluations shall be performed on each supplier to determine the need to schedule additional audits.	R.2.6

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
18.2.3	18.2.3 Audit Schedule The audit schedule shall be developed annually and revised periodically to ensure that coverage is maintained current.	R.3
18.2.4A.:2s	This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.	R.4.1.2
18.2.6C.	C. Lead auditors and auditors shall be qualified in accordance with the requirements of this Sec.	R.6.3
18.2.8D.	D. A summary of the documents reviewed, persons interviewed, and the specific results of the reviews and interviews, that is, a summary of the checklist contents.	R.8.5
18.2.21B.:1s	B. Management of the auditing organization shall evaluate the proficiency of lead auditors annually.	R.21.2.1
SUPPLEMENT I	**SOFTWARE**	**S**
I.2 I.2.1	Requirements . Software Life Cycles, Baselines, and Controls A. for developed or modified software, each Affected Organization shall document and approve a specific software life cycle for each software item prior to development of modification of software.	S.1 S.1.1
I.2.1B. I.2.1B.1.	A. For acquired software the following requirements shall be met: 1. Perform installation tests to ensure that software performs as required in the operational environment.	S.1.2 S.1.2.1
I.2.1C.2.	2. Documentation that the software provides correct results for a specified range of input parameters.	S.1.3.2
I.2.2 I.2.2A.:s1	I.2.2. Software Verification and Software Validation A. Software verification and software validation shall be performed prior to release.	S.2 S.2.1.1
I.2.5A. I.2.5A.1.	A. Functional Requirements Information: 1. A description of the overall nature and purpose of the software.	S.5.1 S.5.1.1
I.2.6. I.2.6.:s1	I.2.6. Software Configuration Management A software configuration management system shall be established to include configuration identification and configuration control and status accounting.	S.6 S.6.1.1

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I.2.6A.2.	2. A unique identification of each software item to be placed under software configuration management.	S.6.2.2
I.2.6B. I.2.6B.1.	A. Configuration control shall include: 1. A release and control process for baseline elements.	S.6.3 S.6.3.1
I.2.7.	I.2.7. Defect Reporting and Resolution A software defect reporting and resolution system shall be implemented.	S.7
SUPPLEMENT II	**SAMPLE CONTROL**	**T**
II.2.1.C	C. Controls shall include specifics on orientation relative to the location that was sampled, as appropriate.	T.1.3
II.2.2 II.2.2.A	II.2.2 Traceability A. Sample identification methods shall ensure that traceability is established and maintained from the samples to applicable implementing documents or other specifying documents.	T.2 T.2.1
II.2.4.C	C. If sample storage is required, then methods shall be established for the control of sample identification that are commensurate with the planned duration and conditions of storage. These methods shall provide for, as applicable:	T.4.3
SUPPLEMENT III	**SCIENTIFIC INVESTIGATIONS**	**U**
III.2 III.2.1 III.2.1A.	III.2 Requirements III.2.1 Planning Scientific Investigations A. Scientific investigations shall be planned in accordance with Section 2.0, Quality Assurance Program.	U.1 U.1.1
III.2.1B.	B. Planning shall be coordinated with organizations providing input to or using the results of the investigation.	U.1.2
III.2.2 III.2.2A.	III.2.2 Performing Scientific Investigations A. Scientific investigations shall be performed using scientific notebooks, implementing documents, or a combination of both.	U.2 U.2.1
III.2.2B. III.2.2B.1.	B. Scientific notebooks shall contain the following: 1. Statement of objective and description of work to be performed, or reference to an approved planning document or implementing document that addresses those topics.	U.2.2 U.2.2.1

DOE/RW-0333P REQ. ID.	SUBJECT DESCRIPTION	SUBJECT CODE
III.2.6 III.2.6A.:1s	III.2.6 Model Development and Use A. The development of models of natural phenomena shall be documented.	U.6 U.6.1.1
SUPPLEMENT V	**CONTROL OF THE ELECTRONIC MANAGEMENT OF DATA**	**V**
V.2 V.2.1 V.2.1A.	V.2 Requirements V.2.1 Control of the Electronic Management of Data The Affected Organization shall establish controls to ensure: A. The completeness and accuracy of the data input.	 V.1 V.1.1
V.2.1B.	B. The completeness and accuracy of subsequent changes to data input.	V.1.2
V.2.1C.	C. The security of the data is maintained including integrity of the data.	V.1.3
V.2.1D.	D. When data is retrieved using a query language, the query shall be checked to ensure it satisfies the Affected Organization's requirements for its intended use.	V.1.4

ATTACHMENT D

DIRECT CAUSE AND ROOT CAUSE CODES

DEFICIENCY CODES

Description	Code	Category
PROCEDURES/IMPLEMENTING DOCUMENTS	1	General
Procedure not used	1 A	Basic
No/incomplete documents/procedure	1 A a	Root
Lost/missing documents/procedure	1 A b	
Procedure difficult to use	1 A c	
Procedure not available or inconvenient to use	1 A d	
Procedure use not required but should be	1 A e	
Inadequate/wrong procedure	1 B	Basic
Typographical error	1 B a	Root
Sequence wrong	1 B b	
Technical facts/data wrong	1 B c	
Requirements:	1 B d	
updates not incorporated	1 B d (1)	
not covered/addressed	1 B d (2)	
Wrong documents/procedure used	1 B e	
Wrong revision used	1 B f	
Implementing documents/process:	1 B g	
not adequate/can't be followed	1 B g (1)	
Incomplete	1 B g (2)	
does not exist	1 B g (3)	
Does not describe *HOW* the requirement will be implemented	1 B g (4)	
Conflicting instructions	1 B h	
Error in following the procedure	1 C	Basic
Format confusing	1 C a	Root
More than one action per step	1 C b	
Multiple references	1 C c	
No signoff space	1 C d	
Checklist misused	1 C e	
Information/Data/Computation wrong or incomplete	1 C f	
Ambiguous instructions	1 C g	
Inadequate limits/parameters	1 C h	
Self imposed requirement—not needed for QARD compliance	1 D	Basic
PERSONNEL—HUMAN PERFORMANCE	2	General
Lack of attention to a task	2 A	Basic
Carelessness	2 A a	Root
Oversight	2 A b	
Work overload	2 A c	
Procedure not used, or used improperly	2 A d	
Wrong revision used	2 A e	
Lack of direction	2 A f	
Lack of Qualification	2 B	Basic
MANAGEMENT SYSTEM	3	General

DEFICIENCY CODES

Description	Code	Category
Standards, Policies, Administrative Controls (SPAC)	3 A	Basic
No SPAC	3 A a	Root
SPAC not used	3 A b	
Inadequate communication of SPAC	3 A c	
SPAC Recently changed	3 A d	
Inadequate drawings/prints	3 A e	
Inadequate accountability	3 A f	
Immediate supervision	3 B	Basic
Inadequate job/task analysis	3 B a	Root
No preparation/planning	3 B b	
Inadequate selection of performer(s)	3 B c	
Individual not qualified	3 B c (1)	
Team selection not balanced/adequate	3 B c (2)	
Performers not trained	3 B d	
No supervision during work	3 B e	
Infrequent task	3 B f	
Communications	3 C	Basic
No/late communication	3 D	Root
Misunderstood verbal communication	3 E	
Audits/Evaluations	3 F	Basic
No Audits/Evaluations	3 F a	Root
Audit checklist misused	3 F b	
TRAINING	4	General
No training	4 A	Basic
Decided not to train	4 A a	Root
No learning objective	4 A b	
Lack of understanding	4 B	Basic
Learning objectives need improvement	4 B a	Root
Lesson plan need improvement	4 B b	
Training instructions need improvement	4 B c	
Testing need improvement	4 B d	
Continued/Refresher training need improvement	4 B e	
Inadequate training methods	4 C	Basic
Incomplete training	4 C a	Root
Inadequate facilities	4 C b	
Continuous training inadequate	4 C c	
Inadequate testing or measure of aptitude	4 C d	
DESIGN/SCIENTIFIC INVESTIGATION	5	General
Design Documents/Scientific Investigation	5 A	Basic
Documents do not exist	5 A a	Root
Data/computation wrong, incomplete, or less than adequate	5 A b	
Requirements:	5 A c	
not identified	5 A c (1)	

DEFICIENCY CODES

Description	Code	Category
incorrectly identified	5 A c (2)	
Scientific investigation not performed per study plan	5 A d	
Problems not anticipated in design or investigation	5 A e	
Equipment environment not considered	5 A f	
Technical Review	5 B	Basic
Review not performed	5 B a	Root
Review inadequate	5 B b	
Reviewer lack of independence	5 B c	
FABRICATION/INSTALLATION	6	General
Fabrication/installation	6 A	Basic
Fabrication/installation error	6 A a	Root
Fabrication/installation not per design	6 A b	
Wrong sequence fabrication/installation	6 A c	
Wrong material	6 A d	
Defective material	6 A e	
Lack of proper tools used for fabrication/installation	6 A f	
Quality Control	6 B	Basic
No inspection	6 B a	Root
Wrong inspection instructions	6 B b	
Wrong inspection technique	6 B c	
RELIABILITY SYSTEM	7	General
Inadequate Preventative Maintenance	7 A	Basic
No preventative maintenance for equipment	7 A a	Root
Inadequate preventative maintenance for equipment	7 A b	
Unreliable Equipment	7 B	Basic
Equipment past design lifetime	7 B a	Root
Equipment repeated failure, previous corrective action inadequate	7 B b	
SOFTWARE	8	General
Computer software controls	8 A	Basic
Inadequate software design	8 A a	Root
Inadequate validation, verification, or testing	8 A b	
Defects:	8 A c	
Inadequate defect report	8 A c (1)	
Inadequate defect resolution	8 A c (2)	
Inadequate software maintenance	8 A d	
Inadequate software identification	8 A e	
Inadequate user information manuals	8 B	Basic
Inadequate control of usage	8 C	
Inadequate data update	8 D	
PROCUREMENT	9	General
Vendor not in the Approved Supplier List	9 A	Basic
Vendor not qualified	9 B	
Receiving inspection	9 C	

DEFICIENCY CODES

Description	Code	Category
No receiving inspection	9 C a	Root
Inadequate Receiving inspection	9 C b	
MISCELLANEOUS OR MULTIPLE AREAS	10	General
Multiple Causes Present	10 A	Basic
Material/Equipment Inadequate	10 B	
Unknown	10 C	
Natural Causes	10 D	
Planned Failure	10 E	